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code of federal regulations

Public Health

ORIGINAL

COMPLETED
533

42

PARTS 1 TO 60
Revised as of October 1, 1982

022-003-94849-0

THE NATIONAL ARCHIVES OF THE UNITED STATES
1934

code of federal regulations

Public Health

42

PARTS 1 TO 60

Revised as of October 1, 1982

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thus: 42 CFR 2.1

Explanation

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

ISSUE DATES

Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16	as of January 1
Title 17 through Title 27	as of April 1
Title 28 through Title 41	as of July 1
Title 42 through Title 50	as of October 1

The appropriate revision date is printed on the cover of each volume.

LEGAL STATUS

The contents of the Federal Register are required to be judicially noticed (44 U.S.C. 1507). The Code of Federal Regulations is prima facie evidence of the text of the original documents (44 U.S.C. 1510).

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The Code of Federal Regulations is kept up to date by the individual issues of the Federal Register. These two publications must be used together to determine the latest version of any given rule.

To determine whether a Code volume has been amended since its revision date (in this case, October 1, 1982), consult the "List of CFR Sections Affected (LSA)," which is issued monthly, and the "Cumulative List of Parts Affected," which appears in the Reader Aids section of the daily Federal Register. These two lists will identify the Federal Register page number of the latest amendment of any given rule.

EFFECTIVE AND EXPIRATION DATES

Each volume of the Code contains amendments published in the Federal Register since the last revision of that volume of the Code. Source citations for the regulations are referred to by volume number and page number of the Federal Register and date of publication. Publication dates and effective dates are usually not the same and care must be exercised by the user in determining the actual effective date. In instances where the effective date is beyond the cut-off date for the Code a note has been inserted to reflect the future effective date. In those instances where a regulation published in the Federal Register states a date certain for expiration, an appropriate note will be inserted following the text.

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What is incorporation by reference? Incorporation by reference was established by statute and allows Federal agencies to meet the requirement to publish regulations in the Federal Register by referring to materials already published elsewhere. For an incorporation to be valid, the Director of the Federal Register must approve it. The legal effect of incorporation by reference is that the material is treated as if it were published in full in the Federal Register (5 U.S.C. 552(a)). This material, like any other properly issued regulation, has the force of law.

What is a proper incorporation by reference? The Director of the Federal Register will approve an incorporation by reference only when the requirements of 1 CFR Part 51 are met. Some of the elements on which approval is based are:

(a) The incorporation will substantially reduce the volume of material published in the Federal Register.

(b) The matter incorporated is in fact available to the extent necessary to afford fairness and uniformity in the administrative process.

(c) The incorporating document is drafted and submitted for publication in accordance with 1 CFR 51.

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JOHN E. BYRNE,
Director,
Office of the Federal Register.

October 1, 1982.

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THIS TITLE

Title 42—PUBLIC HEALTH is composed of three volumes. Volume one (Parts 1-60) contains current regulations issued under Chapter I—Public Health Service (HHS). The second volume (Parts 61-399) contains the remaining regulations issued under Chapter I and all current regulations issued under Chapter III—St. Elizabeths Hospital (HHS). Volume three (Part 400-end) includes all regulations issued under Chapter IV—Health Care Financing Administration (HHS). These volumes represent all current regulations codified under this title of the CFR as of October 1, 1982.

Redesignation tables for Chapter I—Public Health Service, Department of Health and Human Services and Chapter IV—Health Care Financing Administration, Department of Health and Human Services appear in the Finding Aids section of the second and third volumes.

For this volume Linda A. Rice-Johnston was Chief Editor. The Code of Federal Regulations publication program is under the direction of Martha B. Girard, assisted by Robert E. Jordan.

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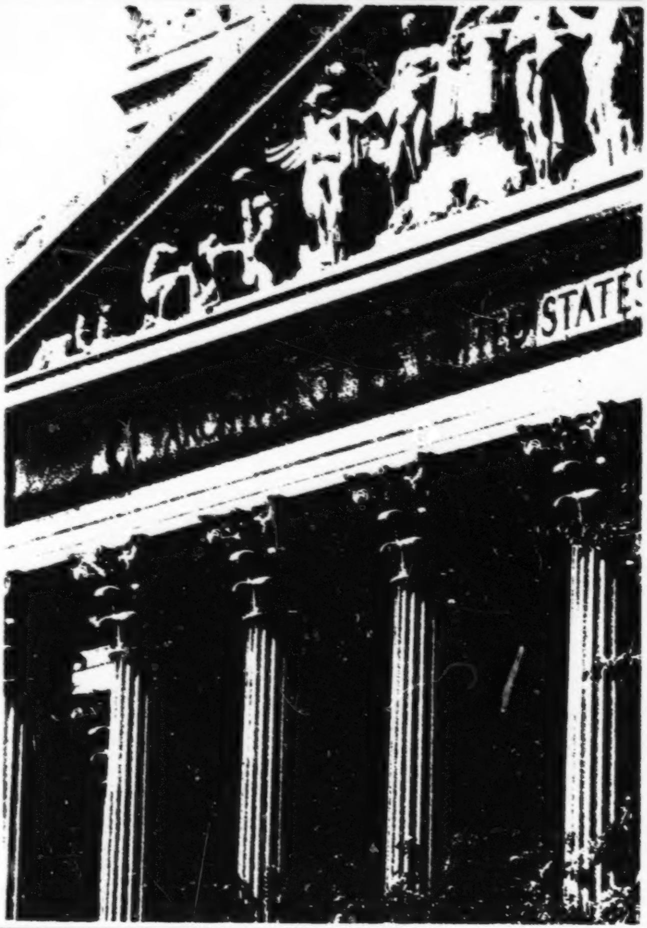

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Title 42—Public Health

(Parts 1 to 60)

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AUTHORITY: Sec. 408, Pub. L. 92-255, 21 U.S.C. 1175, as amended by sec. 303, Pub. L. 93-282; 88 Stat. 137.

SOURCE: 40 FR 27802, July 1, 1975, unless otherwise noted.

Subpart A—Introductory Statement

§ 2.1 Statutory authority—drug abuse.

(a) *Statutory provisions effective May 14, 1974.* Insofar as the provisions of this part pertain to any program or activity relating to drug abuse education, training, treatment, rehabilitation, or research, such provisions are authorized under section 408 of Pub. L. 92-255, the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) as amended by section 303 of Pub. L. 93-282 (88 Stat. 137). That section reads as follows:

> CONFIDENTIALITY OF PATIENT RECORDS
>
> Sec. 408. (a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (c), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.
>
> (b)(1) The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).
>
> (2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:
>
> (A) To medical personnel to the extent necessary to meet a bona fide medical emergency.
>
> (B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.
>
> (C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.
>
> (c) Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.
>
> (d) The prohibitions of this section continue to apply to records concerning any indi-

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vidual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) The Director of the Special Action Office for Drug Abuse Prevention, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Director are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(b) *Amendments effective June 30, 1975.* Effective on the date specified in section 104 of the Drug Abuse Office and Treatment Act of 1972 (June 30, 1975), the first sentence of section 408(g) above, will be amended by striking "Director of the Special Action Office for Drug Abuse Prevention" and inserting in lieu thereof "Secretary of Health and Human Services", and the second sentence of such section will be amended by striking "Director" and inserting "Secretary" in lieu thereof. Also effective on that date, section 408, above, will be further amended by (1) striking out "The" and inserting in lieu thereof "Except as provided in subsection (h) of this section, the" in the first sentence of subsection (g) of such section; and (2) adding at the end of such section the following new subsection:

(h) The Administrator of Veterans' Affairs, through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations established by the Secretary under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from drug abuse. In prescribing and implementing regulations pursuant to this subsection, the Administrator shall, from time to time, consult with the Secretary in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

§ 2.2 Statutory authority—alcohol abuse.

Insofar as the provisions of this part pertain to any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, such provisions are authorized under section 333 of Pub. L. 91-616, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. 4582), as amended by section 122(a) of Pub. L. 93-282, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974 (88 Stat. 131). As so amended, that section reads as follows:

CONFIDENTIALITY OF RECORDS

Sec. 333. (a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b)(1) The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) Whether or not the patient, with respect to whom any given record refered to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

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(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(h) The Administrator of Veterans' Affairs, through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Secretary under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from alcohol abuse or alcoholism. In prescribing and implementing regulations pursuant to this subsection, the Administrator shall, from time to time, consult with the Secretary in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

§ 2.3 Previous regulations as controlling authority.

Attention is called to the interpretative regulations, issued by the Special Action Office for Drug Abuse Prevention (37 FR 24636, November 17, 1972, as revised 38 FR 33744, December 6, 1973, referred to hereinafter in this part as the "previous regulations"). Those regulations have been given a special status as controlling authority by the provisions of section 303(d) of Pub. L. 93-282, as well as the references in the legislative history of that act to the precedents established under section 408 of Pub. L. 92-255. Such references appear at page 11 of House Committee Report No. 93-759 and at page H3563 of the Congressional Record for May 6, 1974. The latter citation is to a detailed analysis of the bill in its final form which was submitted for the Record by its floor manager, Chairman Staggers of the Interstate and Foreign Commerce Committee, when the bill was up for final action by the House of Representatives.

§ 2.4 General purposes.

(a) *Policy objectives.* The purpose of the regulations set forth in this part is to implement the authorizing legislation in a manner that, to the extent practicable, takes into account two streams of legal thought and social policy. One has to do with enhancing the quality and attractiveness of treatment systems. The other is concerned with the interests of patients as citizens, most particularly in regard to protecting their rights of privacy. Within each stream there are cross-currents, and it should come as no surprise that areas of turbulence are to be found at their confluence.

(b) *Limited purpose.* The regulations contained in this part are not intended to direct the manner in which substantive functions, such as research, treatment, and evaluation, should be carried out, but rather to define the minimum requirements for the protection of confidentiality of patient records which must be satisfied in connection with the conduct of those functions in order to carry out the purposes of the authorizing legislation. This does not mean that observance of only the minimum legal requirements is always the wisest course, but in framing these regulations, allowance has necessarily been made for a diversity of emphasis and approach in the many different jurisdictions and by the great variety of public and private agencies which must find a way to function within the limits here prescribed.

§ 2.5 Format.

(a) *Basis and purpose sections.* Each section setting forth rules on any given topic in Subparts B through E of this part is followed by a section setting forth their basis and purpose. In many cases, the basis and purpose section is itself an interpretative rule regarding the legal authority of the rulemakers. In other instances, it summarizes historical or evidentiary material relevant to the validity and interpretation of the section which precedes it.

(b) *Statutory rules fully incorporated.* Although, for convenience of reference, the statutory basis for this part is set out in full in §§ 2.1 and 2.2, the regulations in Subparts B through E of this part are intended to include all of the operative statutory provisions.

§ 2.6 Administration and enforcement in general.

It is not contemplated that any particular agency will be set up specifically to enforce compliance with this part. Programs which receive Federal grants may be monitored for compliance with this and other applicable Federal law as an incident to the grant administration process. Similarly, FDA inspections of methadone programs will include inspection for compliance with this part, which is incorporated by reference in the methadone regulation (21 CFR 310.505).

§ 2.7 Reports of violations.

Any violation may be reported to the United States Attorney for the judicial district in which the violation occurs. Violations on the part of methadone programs may be reported to the regional offices of the Food and Drug Administration. Violations on the part of a Federal grantee or contractor may be reported to the Federal agency monitoring the grant or contract.

Subpart B—General Provisions

§ 2.11 Definitions and usages—Rules.

(a) *Authorizing legislation.* The term "authorizing legislation" means section 408 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) and section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582), as such sections may be amended and in effect from time to time.

(b) *Construction of terms.* The definitions and rules of construction set forth in this section are applicable for the purposes of this part. To the extent that they refer to terms used in the authorizing legislation, they are also applicable for the purposes of such legislation.

(c) *Alcohol abuse.* The term "alcohol abuse" includes alcoholism.

(d) *Drug abuse.* The term "drug abuse" includes drug addiction.

(e) *Diagnosis and treatment.* The terms "diagnosis" and "treatment" include interviewing, counselling, and any other services or activities carried on for the purpose of or as an incident to diagnosis, treatment, or rehabilitation with respect to drug abuse or alcohol abuse, whether or not conducted by a member of the medical profession.

(f) *Program.* (1) The term "program", when referring to an individual or organization, means either an individual or an organization furnishing diagnosis, treatment, or referral for alcohol abuse or drug abuse.

(2) The term "program", when not used in the sense defined in paragraph (f)(1), means a plan or procedure, whether functional or organizational, and whether or not governmental, for dealing with alcohol abuse or drug abuse problems from either an individual or a social standpoint.

(g) *Program evaluation.* The term "program evaluation" means an evaluation of:

(1) The effectiveness, efficiency, compliance with applicable therapeutic, legal, or other standards, or other aspects of the performance, of a program as defined in paragraph (f)(1) of this section, or

(2) The validity, effectiveness, efficiency, practicability, or other aspects of the utility or success of a program in the sense defined in paragraph (f)(2) of this section.

(h) *Program director.* The term "program director" in the case of a program which is an individual means that individual, and in the case of a program which is an organization, the individual, if any, who is the principal, or, in the case of organizations consisting of partners or under the control of a board of directors, board of trustees or other governing body, the individual designated as program director, managing director, or otherwise vested with executive authority with respect to the organization.

(i) *Patient.* The term "patient" means any individual (whether referred to as a patient, client, or otherwise) who has applied for or been given diagnosis or treatment for drug abuse or alcohol abuse and includes any individual who, after arrest on a criminal charge, is interviewed and/or tested in connection with drug or alcohol abuse preliminary to a determination as to eligibility to participate in a treatment or rehabilitation program.

(j) *Patient identifying information.* The term "patient identifying information" means the name, address, social security number, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a patient identifying number assigned by a program.

(k) *Alcohol abuse or drug abuse prevention function.* The term "alcohol abuse or drug abuse prevention function" means any program or activity relating to alcohol abuse or drug abuse education, training, treatment, rehabilitation, or research, and includes any such functions even when performed by an organization whose primary mission is in the field of law enforcement or is unrelated to alcohol or drugs.

(l) The term "person" means an individual, a partnership, a corporation, a trust, a Federal or State governmental agency, or any other legally cognizable entity.

(m) *Service organization.* The term "service organization" means a person which provides services to a program such as data processing, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services.

(n) *Qualified service organization.* The term "qualified service organization" means a service organization which has entered into a written agreement with a program pursuant to which the service organization—

(1) Acknowledges that in receiving, storing, processing, or otherwise dealing with any information from the program about patients in the program, it is fully bound by the provisions of this part;

(2) Undertakes to institute appropriate procedures for safeguarding such information, with particular reference to patient identifying information; and

(3) Undertakes to resist in judicial proceedings any efforts to obtain access to information pertaining to patients otherwise than as expressly provided for in this part.

(o) *Records.* The term "records" includes any information, whether recorded or not, relating to a patient, received or acquired in connection with the performance of any alcohol abuse or drug abuse prevention function, whether such receipt or acquisition is by a program, a qualified service organization, or any other person.

(p) *Communications not constituting disclosure.* The following types of communications do not constitute disclosures of records:

(1) Communications of information within a program between or among personnel having a need for such information in connection with their duties.

(2) Communications between a program and a qualified service organization of information needed by the organization to perform its services to the program.

(3) Communications of information which includes neither patient identifying information nor identifying numbers assigned by the program to patients.

(q) *Previous regulations.* The term "previous regulations" refers to the interpretative regulations issued by the Special Action Office for Drug Abuse Prevention, originally published November 17, 1972, 37 FR 24636, as revised December 6, 1973, 38 FR 33744.

(r) *State law.* The term "State law" refers to the law of a State or other jurisdiction, such as the District of Columbia, as distinguished from Federal law in general. As applied to transactions which do not take place in any State or other similar jurisdiction, the term refers to Federal common law as modified by any applicable Federal statutes and regulations.

(s) *Third party payer.* The term "third party payer" means any organization (or person acting as agent or trustee for an organization or fund) which pays or agrees to pay for diagnosis or treatment furnished or to be furnished to a particular individual, where such payment or agreement to pay is on the basis of an individual relationship between the payer and the patient (or a member of the patient's family in the case of self-and-family insurance coverage or similar arrangements) evidenced by a contract, an insurance policy, a certificate of membership or participation, or similar documentation.

(t) *Funding source.* The term "funding source" means any individual or any public or private organization, including any Federal, State, or local governmental agency, which makes payments in support of a program. A funding source is not, as such, a third party payer, even where its payments are based directly or indirectly on the program's patient load with or without respect to specified categories of eligible persons.

(u) *August 22, 1974 draft.* References to the "August 22, 1974 draft" are to the draft regulations set out in the Advance Notice of Proposed Joint Rulemaking published in the Federal Register on August 22, 1974, 39 FR 30426, by the Department of Health, Education, and Welfare and the Special Action Office for Drug Abuse Prevention.

§ 2.11-1 Definitions and usages—Basis and purpose.

(a) *In general.* The definitions are based upon the legislative history of an experience with the authorizing legislation and are intended as aids to construing the provisions of this part to carry out the purposes of those statutes.

(b) *Coverage of applicants for treatment.* Section 2.11(i) is intended to make it clear that records of the identity and other information about a person whose application is rejected or withdrawn are fully as much covered by this part as records pertaining to a patient actually accepted for treatment.

(c) *Program terminology for patients not controlling.* While many programs prefer to use "client" or some other term instead of "patient" to describe the recipients of their services, it is believed preferable to use terminology in this part which is consistent with that used in the authorizing legislation. It should be clearly understood, however, that the records of any individual who fits the definition set forth in § 2.11(i) are covered, no matter what terminology the program may use to designate his status.

(d) *Origin of "prevention function" terminology.* The definition of alcohol abuse or drug abuse prevention function in § 2.11(k) is adapted from the definition of drug abuse prevention function in section 103(b) of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1103(b)). Although there was no corresponding defined term available to the draftsman of the 1974 amendment to section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and

Rehabilitation Act of 1970 (42 U.S.C. 4582), it is clear from the legislative history that the coverage of alcohol abuse patient records was intended to be fully as wide as the coverage of drug abuse patient records, and the definition in § 2.11(k) reflects that intention.

(e) *Ambiguity of the term "program".* It is recognized that it is ordinarily poor drafting technique to use the same term in senses which are as different, yet related, as those in §§ 2.11(f)(1) and 2.11(f)(2). This part, however, has to be read both in conjunction with the Food and Drug Administration's Methadone Regulation and the Drug Abuse Office and Treatment Act of 1972. The Methadone Regulation (21 CFR 310.505) clearly uses the term "program" in the § 2.11(f)(1) sense. In section 103(b) of the Act (21 U.S.C. 1103(b)), it is clearly used in the § 2.11(f)(2) sense, and the usage in section 408(b)(2)(B) of the Act has from its original enactment been administratively interpreted to include both senses. As used in this part, the context should indicate the intended meanings with sufficient clarity to make this preferable to creating and defining new terminology which would be different from that used in related regulations and the authorizing legislation.

(f) *Construction of disclosures.* Section 2.11(p) is intended to clarify the status of communications which are carried on within a program or between a program and persons or organizations which are assisting it in providing patient care. The authorizing legislation was not intended to prohibit programs from carrying on accepted practices in terms of obtaining specialized services from outside organizations. In conjunction with the definition of qualified service organizations, set forth in § 2.11(n), the provisions of § 2.11(p) should prevent the development of abuses in this area.

§ 2.12 Applicability—Rules.

(a) *In general.* Except as provided in paragraph (b) of this section, this part applies to records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any alcohol abuse or drug abuse prevention functions—

(1) Which is conducted in whole or in part, whether directly or by grant, contract, or otherwise, by any department or agency of the United States,

(2) For the lawful conduct of which in whole or part any license, registration, application, or other authorization is required to be granted or approved by any department or agency of the United States,

(3) Which is assisted by funds supplied by any department or agency of the United States, whether directly through a grant, contract, or otherwise, or indirectly by funds supplied to a State or local government unit through the medium of contracts, grants of any description, general or special revenue sharing, or otherwise, or

(4) Which is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program conducting such functions, or by a way of a tax-exempt status for such program.

(b) *Armed Forces and Veterans' Administration.* (1) The provisions of this part do not apply to any interchange, entirely within the Armed Forces, within those components of the Veterans' Administration furnishing health care to veterans, or between such components and the Armed Forces, of records pertaining to a person relating to a period when such person is or was subject to the Uniform Code of Military Justice.

(2) Except as provided in paragraph (b)(1) of this section, this part applies to any communication between any person outside the Armed Forces and any person within the Armed Forces.

(3) Except as provided in paragraph (b)(1) of this section, this part applies, insofar as it pertains to any drug abuse prevention function, to any communication between any person outside those components of the Veterans' Administration furnishing health care to veterans and any person within such components, until such date as the Secretary of Health and Human Services exercises his authority (conferred by an amendment effective June 30, 1975) to prescribe

regulations under section 408 of Pub. L. 92-255 (21 U.S.C. 1175). After such date, this part applies thereto to such extent as the Administrator of Veterans' Affairs, through the Chief Medical Director, by regulation makes the provisions of this part applicable thereto.

(4) Except as provided in paragraph (b)(1) of this section, this part applies, insofar as it pertains to any alcohol abuse prevention function, to any communication between any person outside those components of the Veterans' Administration furnishing health care to veterans and any person within such components, to such extent as the Administrator of Veterans' Affairs, through the Chief Medical Director, by regulation makes the provisions of this part applicable thereto.

(c) *Period covered as affecting applicability.* The provisions of this part apply to records of identity, diagnosis, prognosis, or treatment pertaining to any given individual maintained over any period of time which, irrespective of when it begins, does not end before March 21, 1972, in the case of diagnosis or treatment for drug abuse or before May 14, 1974, in the case of diagnosis or treatment for alcohol abuse.

(d) *Applicability determined by nature and purpose of records.* The applicability of the provisions of this part is determined by the nature and purpose of the records in question, and not by the status or primary functional capacity of the recordkeeper.

§ 2.12-1 Applicability—Basis and purpose.

(a) The broad coverage provided by § 2.12(a) is appropriate in the light of the remedial purposes of the statutes as well as the practical desirability of certainty and uniformity. Sections 2.12(a)(1) and 2.12(a)(2) simply follow the terms of subsection (a) of the statutes, with some explanatory material for the sake of clarity and explicitness.

(b) Sections 2.12(a)(3) and 2.12(a)(4) are based upon the use by Congress of the phrase "directly or indirectly assisted by any department or agency of the United States". In the light of the multiplicity and extent of Federal programs and policies which can be of assistance to drug and alcoholism programs, this wording strongly suggests an intention to provide the broadest coverage consistent with the literal terms of the statutes. Many programs commence with direct Federal assistance, financial, technical, or both, and later continue with State aid and private, tax-deductible contributions. It would be manifestly contrary to the general policy sought to be effectuated by the legislation if the confidential status of a program's records were to terminate, or even be called into question, by the cessation of direct Federal assistance.

(c) With regard to § 2.12(a)(3), it seems clear that whenever a State or local government is assisted by the Federal government by way of revenue sharing or other unrestricted grants, all of the programs and activities of the State or local government are thereby indirectly assisted, and thus meet that aspect of the statutory criteria for coverage.

(d) Section 2.12(a)(4) follows the doctrine established in *McGlotten v. Connally,* 338 F. Supp. 448 (D.C. D.C., 1972), in which it was held that the deductible status of contributions to an organization constitutes "Federal financial assistance" within the meaning of section 601 of the 1964 Civil Rights Act (42 U.S.C. 2000d). The inclusion of the adjective "indirect" as a modifier of the term "assistance" as used in the provisions of law authorizing this part suggests an intention to provide coverage at least as broad, if not broader than, section 601 of the Civil Rights Act in respect of financial assistance. See, also, *Green v. Connally,* 330 F. Supp. 1150 (D.C. D.C., 1971) aff'd sub. nom. *Coit v. Green,* 404 U.S. 997, 92 S. Ct. 564, 30 L. Ed. 2d 550 (1971).

(e) Section 2.12(b) essentially repeats the interpretation given in § 1401.02(b) of the previous regulation except that it takes account of the special provisions inserted in the new law with reference to the Veterans Administration, and makes clear that the exemption for communications within the military-VA system does not generally apply to records pertaining to civilians.

(f) Section 2.12(c), which deals with the question of how the period covered by any given set of records affects the applicability of these regulations to them, restates the principle set forth in § 1401.02(a) of the previous regulations, and applies it to records in the field of alcohol abuse as well as drug abuse. The authorizing legislation contains no effective date provisions. A construction which would apply the statutes to records of completely closed treatment episodes, records necessarily made and maintained prior to the enactment of the legislation, would create serious administrative problems. It seems doubtful, in any case, whether such records have been "maintained," within the meaning of the statutes, during any period of time after their enactment. On the other hand, if treatment is actually carried on after the enactment of the applicable statute, then all the records should be covered irrespective of when treatment was begun, because such records clearly are being "maintained" after the enactment of the legislation.

(g) Section 2.12(d) has been included to make explicit one of the legal implications of the authorizing legislation, which is cast in terms descriptive of the records which are to be confidential rather than of the recordkeepers on whom a duty is thus imposed. The result is that, for example, where a State agency maintains an individual client record which contains identifying information about a client (i.e., patient) receiving treatment or rehabilitation services for drug abuse, such a record is clearly a record maintained in connection with a drug abuse prevention function, and is subject to the provisions of this part. The fact that the record may also be required by statute or regulations pertaining to eligibility for Federal Financial Participation would in no way exempt the record from the prohibitions and requirements of this part. Thus, it would be unlawful and a violation of these regulations for such a record to be made available to a law enforcement agency, or to determine (without the prior written consent of the client) eligibility for other welfare benefits, or for any other administrative or investigative uses or purposes which would involve or result in an identification of the client to a third party.

§ 2.13 General rules regarding confidentiality—Rules.

(a) *In general.* Records to which this part applies shall be confidential and may be disclosed only as authorized by this part, and may not otherwise be divulged in any civil, criminal, administrative, or legislative proceeding conducted by any Federal, State, or local authority, whether such proceeding is commenced before or after the effective date of this part.

(b) *Unconditional compliance required.* The prohibition upon unauthorized disclosure applies irrespective of whether the person seeking disclosure already has the information sought, has other means of obtaining it, enjoys official status, has obtained a subpoena, or asserts any other justification or basis for disclosure not expressly authorized under this part.

(c) *Information covered by prohibition.* The prohibition on unauthorized disclosure covers all information about patients, including their attendance or absence, physical whereabouts, or status as patients, whether or not recorded, in the possession of program personnel, except as provided in paragraph (d) of this section.

(d) *Crimes on program premises or against program personnel.* Where a patient commits or threatens to commit a crime on the premises of the program or against personnel of the program, nothing in this part shall be construed as prohibiting personnel of the program from seeking the assistance of, or reporting such crime to, a law enforcement agency, but such report shall not identify the suspect as a patient. In any such situation, immediate consideration should be given to seeking an order under Subpart E of this part to permit the disclosure of such limited information about the patient as may be necessary under the circumstances.

(e) *Implicit and negative disclosures prohibited.* The disclosure that a person (whether actual or fictitious) answering to a particular description, name, or other idenfication is not or has not been attending a program, whether over a period of time or on a particular occasion, is fully as much subject to the prohibitions and conditions of this part as a disclosure that such a person is or has been attending such a program. Any improper or unauthorized request for any disclosure of records or information subject to this part must be met by a non-committal response.

(f) *In-patients and residents.* The presence of any in-patient in a medical facility or resident in a residential facility for the treatment of drug or alcohol abuse may be acknowledged to callers and visitors with his written consent. Without such consent, the presence of any in-patient or resident in a facility for the treatment of a variety of conditions may be acknowledged if done in such a way as not to indicate that the patient is being treated for drug or alcohol abuse.

§ 2.13-1 General rules regarding confidentiality—Basis and purpose.

(a) Section 2.13(a) enunciates the general principle of the statutory provisions, and is unchanged from § 1401.03 of the previous regulations.

(b) Sections 2.13(b) and 2.13(c) have been added on the basis of written comments on the draft regulations published August 22, 1974, in which there was a documented report that counsel for a program had advised the program that it could furnish information to the FBI about patients without their written consent and without completing a full judicial proceeding in accordance with Subpart E of this part. Sections 2.13(b) and 2.13(c) should clarify the original intent of the statutes and regulations to the extent of precluding such errors in the future.

(c) In the situation described in § 2.13(d), the desirability of the general prophylactic rule prohibiting disclosures by program personnel about patients regardless of whether such disclosures are from a written record must yield to the practical necessity to permit protection from, and prompt reporting of, criminal acts. In the preface to the first set of regulations issued under 21 U.S.C. 1175, it was emphasized that the operation of that section "in no way creates a sanctuary for criminals." (37 FR 24636, November 17, 1972). Section 2.13(d) is consistent with that contemporaneous administrative construction.

(d) Section 2.13(e) is adapted from § 1401.11 of the August 22, 1974 draft. The suggestion that this part be cited when declining to give information has been deleted on the basis of comments that correctly pointed out that such a citation, if given by an institution or program maintaining some records covered by this part and some not, would serve to identify the records inquired about as pertaining to treatment covered by this part.

(e) Section 2.13(f) merely clarifies the effect of the preceding paragraphs in the special situations to which paragraph (f) relates.

§ 2.14 Penalty for violations—Rules.

(a) *Penalty provided by law.* Any person who violates any provision of the authorizing legislation or any provision of this part shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(b) *Application to subsequent offenses.* Where a defendant has committed one offense under either section authorizing this part or any provision of this part authorized by that section, any offense thereafter committed under the same section or any provision of this part authorized under that section shall be treated as a subsequent offense.

§ 2.14-1 Penalty for violations—Basis and purpose.

(a) Section 2.14 states the criminal penalty provided for in subsection (f) of the sections authorizing this part. It is included in this part for convenience and completeness. Some of the comments received on this section when originally proposed suggested that criminal penalties for violation should include imprisonment, but such a change would have to be made by legislation rather than rulemaking.

(b) Section 2.14(b) clarifies the intention that the "subsequent offense" need not be identical to the first offense, as long as it is committed with respect to the same statutory section. For example, a person whose first offense had consisted of improperly releasing the name of a patient in an alcoholism treatment program would be punishable for a "subsequent offense" if he later gives out information from the diagnostic work-up of an alcoholism patient.

§ 2.15 Minor patients—Rules.

(a) *Definition of minor.* The term "minor" means a person who has not attained the age of 18 years or, in a State where a different age is expressly provided by State law as the age at which a person ceases to be a minor, the age prescribed by the law of such State.

(b) *Consent to disclosure in general.* Except as provided in paragraph (c), of this section, where consent is required for any disclosure under this part, such consent in the case of a minor must be given by both the minor and his parent, guardian, or other person authorized under State law to act in his behalf, but any disclosure made after the patient has ceased to be a minor may be consented to only by the patient.

(c) *Rule when State law authorizes treatment without parental consent.* Whenever a patient, acting alone, has the legal capacity under the applicable State law to apply for and obtain such diagnosis, counselling, administration of medication, or other services as actually are or were provided to him by the program with respect to which he is or was a patient, any consent required for disclosure under this part may be given only by the patient, notwithstanding the fact that the patient may be a minor.

(d) *Initial contacts.* When a minor applies for services under circumstances other than those described in paragraph (c) of this section, the fact of such application may not be disclosed, except as an incident to a communication authorized under paragraph (f) of this section, without consent of the applicant, to the applicant's parent, guardian, or other person authorized under State law to act on behalf of the applicant. When such an applicant refuses consent, it must be explained to the applicant that while he or she has the right (subject to the provisions of paragraph (f) of this section) to withhold such consent, the services applied for cannot be provided without it.

(e) *Collection or attempted collection of payment for services.* Where State law authorizes the furnishing of services to a minor without the consent of the minor's parent or guardian, no inquiry may be made of the parent's or guardian's financial responsibility, and no bill, statement, request for payment, or any other communication in respect of such services may be transmitted directly or indirectly to such parent or guardian, without the express written consent of the patient. Such consent may not be made a condition of the furnishing of services except in the case of a program which is not required by law, and does not in fact hold itself out as willing, to furnish services irrespective of ability to pay.

(f) *Applicant lacking capacity for rational choice.* When, in the judgment of a program director a minor applicant for services, because of extreme youth or mental or physical condition, lacks the capacity to make a rational decision on whether to consent to the notification of a parent or guardian, and the situation of the applicant poses a substantial threat to the life or physical well being of the applicant or any other individual, and such threat might be reduced by communicating the relevant facts to a parent or guardian of the applicant, such facts may be so communicated by the program director or by program personnel authorized by the director to do so.

§ 2.15-1 Minor patients—Basis and purpose.

(a) The statutes authorizing this part are totally silent on the issue of the capacity of a minor to give consent for disclosures, and there is nothing in the legislative history to suggest that the question was ever considered by Congress. The question is, however, one which arises repeatedly, and it is therefore appropriately addressed under the general rulemaking authority conferred by subsection (g) of the authorizing legislation.

(b) Perhaps no legal issues are more highly charged than those affecting the relationship of parent and child. Since Congress has not evidenced an intention to affect this relationship, it is clear that local law should govern, and the task of rulemaking is limited to that of insuring, as far as possible, that the results under Federal law are consistent with local policy.

(c) Where a State has authorized the furnishing of treatment or other services of a given type to a minor without notice to or consent by the parent or guardian, it seems clear that a consistent Federal policy with respect to disclosure requires that consent for any disclosure of the treatment record be given by the minor. This policy, moreover, should not be frustrated by attempts to enforce parental financial responsibility in a situation where the State itself has determined that the minor should have a right to obtain services without involving the parent.

(d) A much more difficult problem is presented in the case of a minor who applies for services in a jurisdiction which has not determined that a minor should have the right to obtain them without parental knowledge or consent. The question may arise as to whether the clinician has an ethical or legal duty to notify the parent which conflicts with a duty of nondisclosure. The rules in § 2.15 are based upon the theory that Federal law should not invalidate a State policy which prohibits treatment without parental consent, but that keeping confidential a mere application for treatment is not ordinarily a sufficient transgression of such a State policy as to require an exception to the general Federal policy prohibiting disclosure of an application for services without the consent of the applicant.

(e) Section 2.15(f) deals with the case of the minor applicant who lacks the capacity to make a rational choice about consenting to disclosure. It is based upon the theory that where a person is actually as well as legally incapable of acting in his own interest, disclosures to a person who is legally responsible for him may be made to the extent that the best interests of the patient clearly so require. Any other rule could subject clinicians to an intolerable choice between violating the provisions of this part on the one hand, or failing to take action to avoid a preventable tragedy involving a minor, on the other. The statutes authorizing this part should not be read as requiring such a choice.

§ 2.16 Incompetent and deceased patients—Rules.

(a) *Incompetent patients other than minors.* Where consent is required for any disclosure under this part, such consent in the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs may be given by the guardian or other person authorized under State law to act in the patient's behalf.

(b) *Deceased patients.* (1) *In general.* Except as provided in paragraph (b)(2) of this section, where consent is required for any disclosure of this part, such consent in the case of records of a deceased patient may be given by an executor, administrator, or other personal representative. If there is no appointment of a personal representative, such consent may be given by the patient's spouse, or if none, by any responsible member of the patient's family.

(2) *Vital statistics.* In the case of a deceased patient, disclosures required under Federal or State laws involving the collection of death and other vital statistics may be made without consent.

§ 2.16-1 Incompetent and deceased patients—Basis and purpose.

Section 2.16 essentially repeats the substance of § 1401.04 of the previous regulations, broadened to reflect the fact that the statutes now allow any consensual disclosures permitted by the regulations, and to cover the situation of deceased patients for whom no formal appointment of an executor, administrator, or other personal representative has been made. Written comments were received to the effect that the power to consent to disclosure in the case of a deceased patient should be limited to a personal representative. The expense of probate or administration in some jurisdictions could cause financial hardship to survivors, and on balance it is believed that where the assets of an estate are insufficient to justify the appointment of a personal representative, the public interest is served by permitting others to consent to disclosure.

§ 2.17 Security precautions—Rules.

(a) *Precautions required.* Appropriate precautions must be taken for the security of records to which this part applies. Records containing any information pertaining to patients shall be kept in a secure room, or in a locked file cabinet, safe, or other similar container, when not in use.

(b) *Policies and procedures.* Depending upon the type and size of the program, appropriate policies and procedures should be instituted for the further security of records. For example, except where this function is personally performed by the program director, a single member of the program staff should be designated to process inquiries and requests for patient information, and a written procedure should be in effect regulating and controlling access by those members of the staff whose responsibilities require such access, and providing for accountability.

§ 2.17-1 Security precautions—Basis and purpose.

The enormous variations in both the size and the type of programs to which this part is applicable preclude the formulation of specific requirements with respect to the physical security of records. Almost any requirement which could be laid down would, under some circumstances, either be impracticable or perverse in its effects. For example, in a facility handling a variety of medical records, all of which are confidential and so marked, a requirement that those pertaining to drug or alcohol treatment be marked in any distinctive way would merely serve to identify such records as pertaining to drug or alcohol treatment—precisely the opposite of the intended result. The purpose of § 2.17, which is based upon § 1401.25 of the previous regulations, is to alert programs to the necessity of exercising due care with respect to the security of patient records.

§ 2.18 Extent of disclosure—Rule.

Any disclosure made under this part, whether with or without the patient's consent, shall be limited to information necessary in the light of the need or purpose for the disclosure.

§ 2.18-1 Extent of a disclosure—Basis and purpose.

(a) Section 2.18 expresses the general principle, which has application in many different contexts, that any disclosure from records covered by this part should be limited to information necessary in the light of the need or purpose for the disclosure. It is identical to § 1401.06 of the previous regulations.

(b) This section should not be misunderstood as imposing a limitation on the scope of records which may or should be made available to health agencies conducting inspections as described in § 2.55. All of the records maintained by a program may be relevant to such inspection. The Congress has determined that disclosure under such circumstances is not a violation of the statutes authorizing this part; where such disclosure is required by Federal or State law, and the inspecting agency is a qualified State health agency as defined in § 2.55(e)(1), it becomes the responsibility of that agency to protect the confidentiality of information it acquires in the course of its lawful activities.

§ 2.19 Undercover agents and informants—Rules.

(a) *Definitions.* As used in this section, § 2.19-1, and §§ 2.67 and 2.67-1,—

(1) The term "undercover agent" means a member of any Federal, State, or local law enforcement or investigative agency whose identity as such is concealed from either the patients or personnel of a program in which he enrolls or attempts to enroll.

(2) The term "informant" means a person who, at the request of a Federal, State, or local law enforcement or investigative agency or officer, carries on observation of one or more persons

enrolled in or employed by a program in which he is enrolled or employed, for the purpose of reporting to such agency or officer information concerning such persons which he obtains as a result of such observation subsequent to such request.

(b) *General prohibition.* Except as otherwise provided in paragraph (c) of this section, or as specifically authorized by a court order granted under § 2.67—

(1) No undercover agent or informant may be employed by or enrolled in any alcohol or drug abuse treatment program;

(2) No supervisor or other person having authority over an undercover agent may knowingly permit such agent to be or remain employed by or enrolled in any such program; and

(3) No law enforcement or investigative officer may recruit or retain an informant with respect to such a program.

(c) *Exceptions.* The enrollment of a law enforcement officer in a treatment program shall not be deemed a violation of this section if (1) such enrollment is solely for the purpose of enabling the officer to obtain treatment for his own abuse of alcohol or drugs, and (2) his status as a law enforcement officer is known to the program director.

§ 2.19-1 Undercover agents and informants—Basis and purpose.

(a) In many instances, persons who are patients in treatment programs are making their first tentative efforts toward re-integration into productive society. They may be both vulnerable and suspicious, and the presence in a treatment program of undercover law enforcement agents or informants can have a devastating effect on the program's morale and therapeutic effectiveness. Moreover, it would appear that the purpose of such agents or informants may be to obtain precisely the type of personal information which might be revealed by inspection of counselor notes and other patient records maintained by the program. Thus, the placing of an undercover agent or informant in a program, either as a patient or as an employee, would appear to be contrary to the purposes for which the provisions of law authorizing this part were enacted, and properly subject to prohibition under regulations expressly authorized to carry out those purposes.

(b) From a policy standpoint, § 2.19 is based on the reasoning that while the use of undercover agents and informants in treatment programs is ordinarily to be avoided, there may occasionally arise circumstances where their use may be justified. Accordingly, where a showing is made in an application for an order under § 2.67 that the criteria set forth in that section are satisfied, the court may grant such an order.

(c) When this section of the regulations was proposed, numerous written comments were received urging that there be an absolute prohibition on the use of undercover agents and informants, and most of the witnesses at the hearings who addressed the issue at all testified to the same effect. A number of comments were received to the effect that § 2.19 should be dropped altogether, but this request was always clearly and often explicitly predicated on the assumption that failure to say anything about undercover agents and informants would make their use illegal. Our view is to the contrary: We think that the statutes, standing alone, do not prohibit the practice, and thus that in the absence of a specific prohibition in these regulations, the use of undercover agents and informants in treatment programs would not be unlawful. Since this is a view which we believe to be shared by the law enforcement and investigative agencies which are affected by § 2.19, there is as a practical matter no alternative to predicating these regulations upon its correctness.

(d) However desirable it may be to limit the use of undercover agents and informants in treatment programs, we think a strong argument can be made against our power to impose an absolute prohibition. To the extent that the practice is susceptible to regulation through the rulemaking process at all, it is on the theory that it opens the way to disclosure of information which is or should be in program records, and thus is contrary to the purposes of the statutes. Since subsection

(g) of the statutes confers express rulemaking authority to carry out these purposes, regulation of the use of undercover agents and informants is a proper subject for the exercise of that authority. But even the express statutory prohibition against direct disclosure of the content of patient records is subject to the power of the courts to authorize such disclosure under subsection (b)(2)(C) of the statutes. It seems difficult to argue that Congress intended to confer on rulemaking agencies the authority to impose an absolute prohibition even though its own restrictions (other than those on disclosures of patient identifiers from secondary records) are subject to being set aside by court order in particular cases. Since we have not attempted to exercise such an authority, it is not necessary to decide at this time whether it was conferred.

(e) A careful reading of the definitions set forth in § 2.19(a) is crucial to an understanding of the prohibitions which are imposed by § 2.19. Objections to the section were made informally but vigorously on behalf of the Drug Enforcement Administration, on the ground that the testimony of informants or undercover agents is frequently if not normally essential to the successful prosecution of cases arising under the Controlled Substances Act. It was said that in the form originally proposed, the section would cut off from treatment those who might agree to cooperate with law enforcement authorities, a result both inhumane and counterproductive. As the definition of an informant is intended to make clear, however, it is his function vis-a-vis personnel and fellow patients in the program in which he is enrolled which is controlling, and not his relationship, *per se,* with an investigative agency.

(f) Finally, the definition of informant is intended to clarify the distinction between an informant and an ordinary witness. It is the element of prearrangement which is crucial. In one of the comments received on § 2.19 as proposed, it was urged that treatment programs should be considered as sanctuaries, but such a result was explicitly disclaimed in the initial publication of the previous regulations (37 FR 24636). In so saying, we are by no means insensitive to the anxieties repeatedly expressed in both testimony and comments on this section, but we believe that the prohibition contained in § 2.19 and the procedures and criteria set forth in § 2.67 provide a measure of relief which is consistent with the structure and intent of the underlying statutes.

§ 2.20 Identification cards—Rules.

(a) *Required use prohibited.* No program may require or request any patient to carry in his or her possession, while away from the program premises, an identification card or other form of identification which is issued by the program or which would tend to identify the bearer as a participant in it or any similar program.

(b) *Conditions of voluntary use.* Nothing in this section prohibits a program from issuing an identification card to a patient if the patient's counsellor or other authorized member of the program staff has explained to the patient that acceptance and use of the card is entirely voluntary and that neither an initial rejection nor a subsequent discontinuation of its use will in any way prejudice his or her record or standing in the program. In the case of any patient to whom an identification card or similar device was issued prior to the effective date of this section, or subsequent thereto in violation of this section, a counsellor or other authorized member of the program staff shall explain to the patient his right to turn it in without prejudice at any time.

(c) *On-premises exemption.* Nothing in this section prohibits a program from maintaining and using on its premises cards, photographs, tickets, or other devices, or using passwords or other information, to assure positive identification of patients, correct recording of attendance or medication, or for other proper purposes, as long as no pressure is brought on any patient to carry any such device when away from the program premises.

§ 2.20-1 Identification cards—Basis and purpose.

Section 2.20 is in furtherance of one of the basic purposes of the statutes authorizing this part, namely, protection of patients from improper disclosure of their status as such. Regrettably, there appear to be areas where possession of a treatment program identification card can be prejudicial to a person under arrest or subjected to a search. In any part of the country, the accidental display or circulation of such a card by reason of its loss or theft could have adverse consequences for a variety of reasons. Since programs have other means of achieving the ends which identification cards are meant to serve, patients who do not wish to assume whatever risks may be involved in carrying such cards should not be compelled to do so.

§ 2.21 Disposition of discontinued program records—Rules.

(a) *General rule.* When a program discontinues operations or is taken over or acquired by another program, its records to which this part applies with respect to any patient may, with the written consent of that patient, be turned over to the acquiring program or, if none, to any other program specified in the patient's consent. Except as otherwise provided in this section, any records to which this part applies, but for the transfer of which patient consent is not obtained, shall be either completely purged of patient identifying information, or destroyed. If any effort to obtain consent for transfer is made, it shall be by means which minimize the likelihood of accidental or incidental disclosure to any third party of the patient's identity as such.

(b) *Retention period.* Where records are required by law to be kept for a specified period, and such period does not expire until after the discontinuation or acquisition of the program, and patient consent for their transfer is not obtained, such records shall be sealed in envelopes or other containers marked or labelled as follows: "Records of [insert name of program] required to be maintained pursuant to [insert citation to law or regulation requiring that records be kept] until a date not later than December 31, [insert appropriate year]." The same procedure may be followed when it is determined to retain records for the period of any applicable statute of limitations.

(c) *Custodial retention.* Records marked and sealed in accordance with paragraph (b) of this section may be held by any lawful custodian, but may be disclosed by such custodian only under such circumstances and to such extent as would be permissible for the program in which they originated. As soon as practicable after the date specified on the label or legend required to be affixed pursuant to paragraph (b) of this section, the custodian shall destroy the records. In the case of any program terminated by reason of bankruptcy, the expense of compliance with this paragraph shall be an expense of administration of the bankrupt estate.

§ 2.21-1 Disposition of discontinued program records—Basis and purpose.

While arguments can be made for requiring the destruction of records at the conclusion of their useful clinical life, there is wide disagreement on its span, and there are in addition research considerations which argue for an even longer period of retention. Except in the case of discontinued programs, it therefore seems best to leave this issue for determination by the programs concerned.

§ 2.22 Former employees and others—Rules.

The prohibitions of this part on disclosure of patient records or information contained therein apply to all individuals who are personnel of treatment programs, researchers, auditors, evaluators, service organizations, or others having access to such records or information, and continue to apply to such individuals with respect to such records or information after the termination of their employment or other relationship or activity giving rise to such access.

§ 2.22-1 Former employees and others—Basis and purpose.

The probition contained in § 2.22 is arguably an interpretation of the authorizing legislation which would be necessary as a matter of law even in the absence of this part; its validity as an exercise of the rulemaking power conferred by subsection (g) of the authorizing legislation seems beyond dispute.

§ 2.23 Relationship to State laws—Rules.

The enactment of the provisions of law authorizing this part was not intended to preempt the field of law covered thereby to the exclusion of State laws not in conflict therewith. If a disclosure permitted under the provisions of this part, or under a court order issued pursuant thereto, is prohibited under State law, nothing in this part or in the provisions of law authorizing this part may be construed to authorize any violation of such State law. No State law, however, may either authorize or compel any disclosure prohibited by this part.

§ 2.23-1 Relationship to State laws—Basis and purpose.

Section 2.23 sets forth publicly an interpretation which, in informal communications, has consistently been given to 21 U.S.C. 1175 since its original enactment, and clearly has equal applicability to 42 U.S.C. 4582.

§ 2.24 Relationship to section 303(a) of Public Health Service Act and section 502(c) of Controlled Substances Act—Rules.

(a) *Research privilege description.* In some instances, there may be concurrent coverage of a program or activity by the provisions of this part and by a regulation or other administrative action under section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)). The latter two provisions of law, referred to hereinafter in this section as the research privilege sections, confer on the Secretary of Health and Human Services, and on the Attorney General, respectively, the power to authorize researchers to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subject of such research. The Secretary of Health and Human Services may grant this privilege with respect to any "research on mental health, including research on the use and effect of alcohol and other psychoactive drugs." The Attorney General's power is conferred as part of a section authorizing research related to enforcement of laws under his jurisdiction concerning substances which are or may be subject to control under the Controlled Substances Act, but is not expressly limited to such research. Regardless of whether a grant of research privilege is made by the Secretary or by the Attorney General, it is expressly provided that persons who obtain it "may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify" the subjects of research for which the privilege was obtained.

(b) *Comparison with authority for this part.* Although they deal, in a sense, with the same subject matter, and may on occasion concurrently cover the same transactions, it is important to note the differences between the research privilege sections (21 U.S.C. 872(c) and 42 U.S.C. 242a(a)) and the provisions of law (21 U.S.C. 1175 and 42 U.S.C. 4582) which authorize this part. Briefly, these differences are as follows:

(1) Although they contain broad grants of express rulemaking authority, the provisions of law by which this part is authorized are self-executing in the sense that they are operative irrespective of whether the rulemaking authority is exercised. The protection afforded by the research privilege sections, on the other hand, can only come into existence as a result of affirmative administrative action.

(2) The provisions of law authorizing this part, as well as the provisions of this part itself, impose affirmative duties with respect to the records to which they apply, and the violation of such duties is subject to criminal penalties. To the extent that a privilege is thereby created, it grows out of the duties thus imposed. The research privilege sections, by contrast, impose no duties by their own terms, and if any duties are implied from their existence, they would have to be enforced on the basis of an implicit civil

liability for damages or by equitable relief, as there are no criminal or administrative sanctions available.

(3) The exercise of the authority conferred by the research privilege sections is subject to administrative discretion, whereas in the case of the duties imposed under this part there is judicial discretion, within the limits and subject to procedures and criteria prescribed by statute and regulation, to grant relief in particular cases.

(c) *Grant of research privilege not affected by (b)(2)(C) order.* The issuance of an order under subsection (b)(2)(C) of either of the sections authorizing this part (21 U.S.C. 1175 and 42 U.S.C. 4582) in no way affects the continuing effectiveness of any exercise of the authority of the Secretary of Health and Human Services under 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) or the Attorney General under section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)).

§ 2.24-1 Relationship to section 303(a) of Public Health Service Act and section 502(c) of Controlled Substances Act—Basis and purpose.

(a) In Pub. L. 93-282, the Congress expressly amended (by sections 122(a) and 303(a), 88 Stat. 131 and 137) the provisions of law which authorize this part, expressly amended (by section 122(b), 88 Stat. 132) the research privilege section under the Secretary's jurisdiction, and made explicit reference (in section 303(d), 88 Stat. 139) to the regulations previously issued by the Special Action Office for Drug Abuse Prevention reconciling the provisions of section 408 of the Drug Abuse Office and Treatment Act of 1972 with the provisions of the research privilege sections. When the bill which became Pub. L. 93-282 was before the House of Representatives for its last Congressional consideration before transmission to the President, its floor manager, Chairman Staggers of the Committee on Interstate and Foreign Commerce, inserted in the Record a detailed analysis of the bill in its final form (Congressional Record, daily edition, May 6, 1974, page H3563). This analysis contained the following paragraph:

> The relationship of section 303(a) of the Public Health Service Act, authorizing the administrative grant of absolute confidentiality for research, to section 408 of the Drug Abuse Office and Treatment Act of 1972, requiring that Federally-connected drug abuse patient records generally be kept confidential, has been correctly described in an interpretative regulation, 21 CFR 1401.61 and 1401.62, which was upheld in *People v. Newman*, 32 N.Y. 2d 379, [reversing] 336 N.Y.S. 2d 127, 298, N.E. 2d 651 (1973); *certiorari* denied, [414] U.S. [1163], 94 S. Ct. 927, [39 L. Ed. 2d 116] (1974). For that reason, among others, section 303(d) of the Senate amendment expressly continues the effectiveness of the current regulation promulgated by the Director of the Special Action Office for Drug Abuse Prevention. Thus, although section 502(c) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 is not explicitly referred to in this legislation, the congressional intent is clear that the authority conferred by that section was not modified by Pub. L. 92-255, and is not intended to be modified by the bill now before the House.

(b) Sections 2.24 and 2.61 restate, in substance, the interpretative rules (§§ 1401.61 and 1401.62 of the previous regulations) referred to in the passage quoted in paragraph (a) of this section, modified to reflect the amendment made to section 303(a) of the Public Health Service Act (42 U.S.C. 242(a)) by Pub. L. 93-282.

Subpart C—Disclosures With Patient's Consent

§ 2.31 Written consent required—Rules.

(a) *Form of consent.* Except as otherwise provided, a consent for a disclosure under this part must be in writing and must contain the following:

(1) The name of the program which is to make the disclosure.

(2) The name or title of the person or organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose or need for the disclosure.

(5) The extent or nature of information to be disclosed.

(6) A statement that the consent is subject to revocation at any time except to the extent that action has been taken in reliance thereon, and a specification of the date, event, or con-

dition upon which it will expire without express revocation.

(7) The date on which the consent is signed.

(8) The signature of the patient and, when required under § 2.15, the signature of a person authorized to give consent under that section; or, when required under § 2.16, the signature of a person authorized to sign under that section in lieu of the patient.

(b) *Duration of consent.* Any consent given under this subpart shall have a duration no longer than that reasonably necessary to effectuate the purpose for which it is given.

(c) *Disclosure prohibited with deficient consent.* No program may disclose any information on the basis of a consent form—

(1) Which on its face substantially fails to conform to any of the requirements set forth in paragraph (a), of this section, or

(2) Which is known, or in the exercise of reasonable care should be known, to the responsible personnel of the program to be materially false in respect to any item required to be contained therein pursuant to paragraph (a) of this section.

(d) *Falsification prohibited.* No person may knowingly make, sign, or furnish to a program any consent form which is materially false with respect to any item required to be contained therein pursuant to paragraph (a) of this section.

§ 2.31-1 Written consent required—Basis and purpose.

(a) The use of a consent form containing all of the elements specified in § 2.31(a) is necessary to assure compliance with the requirements of this subpart. Under § 1401.21 of the previous regulations, a much more abbreviated form was permissible, because the circumstances under which any consent could be given were very strictly limited. Now that the authorizing legislation permits disclosure with consent "to such extent, under such circumstances, and for such purposes as may be allowed under regulations," the consent form should show on its face information sufficient to indicate compliance with the regulations.

(b) Sections 2.31(b), 2.31(c), and 2.31(d) are an exercise of the general rulemaking authority in subsection (g) of the authorizing legislation. Section 2.31(c) imposes a legal liability on programs and their personnel for disclosure of information on the basis of a materially deficient consent, and § 2.31(d) imposes liability on any person who submits a falsified consent form to a program.

§ 2.32 Prohibition on redisclosure—Rules.

(a) *Notice to accompany disclosure.* Whenever a written disclosure is made under authority of this subpart, except a disclosure to a program or other person whose records pertaining to the patient are otherwise subject to this part, the disclosure shall be accompanied by a written statement substantially as follows: "This information has been disclosed to you from records whose confidentiality is protected by Federal law. Federal regulations (42 CFR Part 2) prohibit you from making any further disclosure of it without the specific written consent of the person to whom it pertains, or as otherwise permitted by such regulations. A general authorization for the release of medical or other information is NOT sufficient for this purpose." An oral disclosure may be accompanied or followed by such a notice.

(b) *Consent required for redisclosure.* A person who receives information from patient records and has been notified substantially in accordance with paragraph (a) of this section is prohibited from making any disclosure of such information except with the specific written consent of the person to whom it pertains, or as otherwise permitted under this part.

(c) *Restriction on redisclosure.* Whenever information from patient records is needed by any person, such information must be obtained directly from the program maintaining such records and not from another person to whom disclosure thereof has been made, except where the initial disclosure was intentionally and expressly made for the purpose of redisclosure (as for example in the case of an employment agency), or the information is no longer available from the program and redisclosure is not prohibited by any other provision of this part.

§ 2.32-1 Prohibition on redisclosure—Basis and purpose.

(a) Section 2.32 is intended to provide a reasonable protection against redisclosure of information disclosed with consent in accordance with this subpart. There is, of course, no problem where the information becomes part of a record which it itself subject to this part because it is maintained in connection with the performance of a covered substance abuse prevention function. The difficulty arises when the disclosure is made to those whose records are not otherwise affected by this part. To attempt to make all of the provisions of this part applicable to such recipients with respect to such information might raise serious problems of legality, administrative feasibility, and fairness, but where they are given actual notice that specific patient consent is normally required for redisclosure, we think they can and should be bound by it.

(b) Oral disclosures are not mandatorily covered because they should rarely be made to any recipient with whom the program does not have a continuing relationship. Where such a relationship exists or the program is otherwise satisfied that the recipient understands and will respect the confidential nature of the information supplied, there seems no need to add to the already heavy load of paperwork with which programs must contend.

§ 2.33 Diagnosis, treatment, and rehabilitation—Rules.

(a) *Disclosure authorized.* Where consent is given in accordance with § 2.31, disclosure of information subject to this part may be made to medical personnel or to treatment or rehabilitation programs where such disclosure is needed in order to better enable them to furnish services to the patient to whom the information pertains.

(b) *Traveling, incarcerated, or hospitalized patients on medication.* Where a patient on medication is at a distance from his normal residence or treatment program or is incarcerated or hospitalized, or is otherwise unable to deliver a written consent to his treatment program at the time the disclosure is needed, confirmation of the patient's status and information necessary to appropriately continue or modify his medication may be given to medical personnel in a position to provide services to the patient upon the oral representation of such personnel that the patient has requested medication and consented to such disclosure. Any program making a disclosure in accordance with this paragraph shall make a written memorandum showing the name of the patient, or the patient's case number assigned by the program, the date and time the disclosure was made, the information disclosed, and the names of the individuals by whom and to whom it was made.

§ 2.33-1 Diagnosis, treatment, and rehabilitation—Basis and purpose.

(a) Section 2.33(a) is a restatement of the policy set forth in § 1401.22(a) of the previous regulations, expanded to make explicit reference to nonmedical counselling and other treatment and rehabilitative services.

(b) Section 2.33(b) clarifies the corresponding provision in § 1401.22(a) of the previous regulations by specifying how and through whom oral consent can be given, and limiting the disclosure to that necessary to determine appropriate medication.

§ 2.34 Prevention of certain multiple enrollments—Rules.

(a) *Definitions.* For the purposes of this section and § 2.55—

(1) The terms "administer", "controlled substance", "dispense", "maintenance treatment", and "detoxification treatment" shall respectively have the meanings defined in paragraphs (2), (6), (10), (27), and (28) of section 102 of the Controlled Substances Act (21 U.S.C. 802).

(2) The term "program" means a program which offers maintenance treatment or detoxification treatment.

(3) The term "permissible central registry" means a qualified service organization which collects or accepts, from two or more programs (referred

to hereinafter as member programs) all of which are located either within a given State or not more than 125 miles from the nearest point on the border of such State, patient identifying information about persons applying for maintenance treatment or detoxification treatment for the purpose of enabling the member programs to prevent any individual from being concurrently enrolled in more than one such program.

(b) *Use of central registries prohibited except as expressly authorized.* The furnishing of patient identifying information by a program to any central registry which fails to meet the definition of a permissible central registry set forth in paragraph (a)(3) of this section is prohibited, and the furnishing of patient identifying information to or by any central registry except as authorized in this section is prohibited. Information pertaining to patients held by a central registry may be furnished or used in accordance with paragraphs (e), (f), and (g) of this section for the purpose of preventing multiple enrollments, but may not be otherwise furnished or used in connection with any legal, administrative, supervisory, or other action with respect to any patient.

(c) *Safeguards and procedures required.* To minimize the likelihood of disclosures of information to impostors or others seeking to bring about unauthorized or improper disclosure, any communications carried on by programs pursuant to this section must be conducted (1) by authorized personnel designated in accordance with § 2.17(b), and (2) in conformity with procedures established in accordance with that section.

(d) *Disclosures with respect to patients in treatment.* A member program may supply patient identifying information and information concerning the type of drug used or to be used in treatment and the dosage thereof, with relevant dates, to a permissible central registry with respect to any patient—

(1) When the patient is accepted for treatment,

(2) When the type or dosage of the drug is changed, and

(3) When the treatment is interrupted, resumed, or terminated.

(e) *Disclosures with respect to applications.*— When any person applies to a program for maintenance treatment or detoxification treatment, then for the purpose of inquiring whether such person is currently enrolled in another program for such treatment, the program may furnish patient identifying information with respect to such person—

(1) To any permissible central registry of which the program is a member, and

(2) To any other program which is not more than 200 miles distant and which is not a member of any central registry of which the inquiring program is a member.

(f) *Program procedure in case of apparent concurrent enrollment.* When an inquiry pursuant to paragraph (e)(2) of this section is made of another treatment program and its response is affirmative, the two programs may engage in such further communication as may be necessary to establish whether an error has been made, and if none, the programs should proceed in accordance with sound clinical practice and any applicable regulations pertaining to the type of treatment involved.

(g) *Registry procedure in case of apparent concurrent enrollment.* When an inquiry pursuant to paragraph (e)(1) of this section is made of a permissible central registry and its response is affirmative, it may advise the inquiring program, of the name, address, and telephone number of the other program, or it may advise the other program of the identity of the patient and the name, address, and telephone number of the inquiring program, or it may do both, and in any case the two programs may then communicate as provided in paragraph (f) of this section.

(h) *Advice to patients.* When the policies and procedures of any program involve any disclosures pursuant to this section, before any patient is accepted for or continued in treatment (other than detoxification treatment) after September 30, 1975, written consent in accordance with § 2.31 shall be obtained. Such consent shall set forth a current list of the names and addresses either of any programs or of any central registries to which such disclosures will be made. Notwithstanding the requirement of § 2.31(a)(2), such consent shall be effective with respect to any other such program thereafter established within 200 miles, or any registry serving such programs, and shall so state. Such consent shall be effective for as long as the patient remains enrolled in the program to which it is given.

§ 2.34-1 Prevention of certain multiple enrollments—Basis and purpose.

Section 2.34 is based upon § 1401.43 of the previous regulations. It was omitted from the August 22, 1974 draft, but comments on the omission made it clear that in certain areas of the country, central registries are a functional component of the treatment system, and that regulations to guide their operations are needed.

§ 2.35 Legal counsel for patient—Rules.

When a bona fide attorney-client relationship exists between an attorney-at-law and a patient, disclosure of any information in the patient's records may be made to the attorney upon the written application of the patient endorsed by the attorney. Information so disclosed may not be further disclosed by the attorney.

§ 2.35-1 Legal counsel for patient—Basis and purpose.

Section 2.35 simplifies and broadens the statement of the policy embodied in § 1401.25 of the previous regulations. Its purpose is to assure the availability to the attorney, with his client's consent, of any information needed as a basis for advice and counsel. The purpose of the prohibition on further disclosure by the attorney is to guard against the possibility that the attorney might be forced to serve as a conduit for otherwise prohibited disclosures to third parties. Ordinarily, the attorney-client privilege would suffice, but that privilege is subject to waiver by the client, whereas this prohibition is not. Where there is a need for disclosure to a third party of any given information about any patient, this prohibition in no way affects the availability of other sections of this part to authorize such disclosure by the program.

§ 2.36 Patient's family and others—Rule.

Where consent is given in accordance with § 2.31, information evaluating his current or past status in a treatment program may be furnished to any person with whom the patient has a personal relationship unless, in the judgment of the person responsible for the patient's treatment, the disclosure of such information would be harmful to the patient.

§ 2.36-1 Patient's family and others—Basis and purpose.

Section 2.36 expresses the same policy as was embodied in § 1401.27 of the previous regulations, broadened to reflect the expanded authority for consensual disclosure under the authorizing legislation.

§ 2.37 Third-party payers and funding sources—Rules.

(a) *Acquisition of information.* Disclosure of patient information to third-party payers or funding sources may be made only with the written consent of the patient given in accordance with § 2.31 and any such disclosure must be limited to that information which is reasonably necessary for the discharge of the legal or contractual obligations of the third-party payer or funding source.

(b) *Prohibition on disclosure.* Where a funding source or third-party payer maintains records of the identity of recipients of treatment or rehabilitation services for alcohol or drug abuse such records are, under the authorizing legislation, maintained in connection with the performance of an alcohol or drug abuse prevention function and are subject to the restrictions upon disclosure set forth in this part.

§ 2.37-1 Third-party payers and funding sources—Basis and purpose.

Section 2.37 is based upon the general authority to prescribe regulations to carry out the purposes of the authorizing legislation. The great diversity of contractual arrangements and legal requirements under which the operations of third-party payers and funding sources are carried on precludes the prescription of detailed records management instructions in these regulations, even if that were otherwise desirable. The general principles set forth in § 2.37, however, should clarify the question of coverage, and where coverage exists, provide a standard which will minimize the likelihood of violations. See also § 2.12-1(g).

§ 2.38 Employers and employment agencies—Rules.

(a) *Disclosure permitted.* Where consent is given in accordance with § 2.31, a program may make disclosures in accordance with this section.

(b) *Eligible recipients.* A program may make disclosures under this section to public or private employment agencies, employment services, or employers.

(c) *Scope of disclosure.* Ordinarily, disclosures pursuant to this section should be limited to a verification of the patient's status in treatment or a general evaluation of progress in treatment. More specific information may be furnished where there is a bona fide need for such information to evaluate hazards which the employment may pose to the patient or others, or where such information is otherwise directly relevant to the employment situation.

(d) *Criteria for approval.* A disclosure under this section may be made if, in the judgment of the program director or his authorized representative appointed as provided in § 2.17(b), the following criteria are met:

(1) The program has reason to believe, on the basis of past experience or other credible information (which may in appropriate cases consist of a written statement by the employer), that such information will be used for the purpose of assisting in the rehabilitation of the patient and not for the purpose of identifying the individual as a patient in order to deny him employment or advancement because of his history of drug or alcohol abuse.

(2) The information sought appears to be reasonably necessary in view of the type of employment involved.

§ 2.38-1 Employers and employment agencies—Basis and purpose.

Section 2.38 is based on the rulemaking power conferred by subsection (b)(1) of the authorizing legislation, and is adapted from § 1401.26 of the previous regulations. Its purpose is to allow disclosures reasonably necessary and appropriate to facilitate the employment of patients and former patients, while protecting patients against unnecessary or excessively broad disclosures. It was urged in a comment received on the August 22, 1974 draft that disclosures to employers be flatly prohibited on the ground that the employer's sole legitimate concern is with on-the-job performance. While we are not unsympathetic to this view, a countervailing consideration is that in the case of an employee or applicant who is known by the employer to have a problem with drugs or alcohol, knowledge by the employer of a genuine effort by the employee to deal with it can make the difference between a job and no job.

§ 2.39 Criminal justice system referrals—Rules.

(a) *Consent authorized.* Where participation by an individual in a treatment program is made a condition of such individual's release from confinement, the disposition or status of any criminal proceedings against him or the execution or suspension of any sentence imposed upon him, such individual may consent to unrestricted communication between any program in which he is enrolled in fulfillment of such condition and (1) the court granting probation, or other post-trial or pretrial conditional release, (2) the parole board or other authority granting parole, or (3) probation or parole officers responsible for his supervision.

(b) *Duration of consent.* Where consent is given for disclosures described in paragraph (a) of this section, such consent shall expire sixty days after it is given or when there is a substantial change in such person's status, whichever is later. For the purposes of this section, a substantial change occurs in the status of a person who, at the time such consent is given, has been—

(1) Arrested, when such person is formally charged or unconditionally released from arrest;

(2) Formally charged, when the charges have been dismissed with prejudice, or the trial of such person has been commenced;

(3) Brought to a trial which has commenced, when such person has been acquitted or sentenced;

(4) Sentenced, when the sentence has been fully executed.

(c) *Revocation of consent.* An individual whose release from confinement, probation, or parole is conditioned upon his participation in a treatment program may not revoke a consent given by him in accordance with paragraph (a) of this section until there has been a formal and effective termination or revocation of such release from confinement, probation, or parole.

(d) *Restrictions on redisclosure.* Any information directly or indirectly received pursuant to this section may be used by the recipients thereof only in connection with their official duties with respect to the particular individual with respect to whom it was acquired. Such recipients may not make such information available for general investigative purposes, or otherwise use it in unrelated proceedings or make it available for unrelated purposes.

§ 2.39-1 Criminal justice system referrals—Basis and purpose.

(a) On the basis of extensive written comment and oral communications received on the subject matter of § 2.39 as proposed in the May 9, 1975 notice (designated as § 2.40 in that notice), we have concluded that the latitude allowed and the conditions imposed in § 2.39 as set forth above are necessary and proper to effectuate the purposes of the authorizing legislation.

(b) From a legal standpoint, it seems highly doubtful whether, in a proceeding to revoke probation or parole, the due process requirements laid down in *Morrissey v. Brewer,* 408 U.S. 471, 92 S.Ct. 2593, 33 L.Ed.2d 484 (1972) and *Gagnon v. Scarpelli,* 411 U.S. 778, 93 S.Ct. 1756, 36 L.Ed. 2d 636 (1973) could be met by an unsupported general evaluation by a treatment program to the effect that a patient's status or progress in treatment was unsatisfactory. Thus, if such an evaluation were all that could be communicated by a program about a particular patient's conduct during the period he was in treatment, a condition requiring satisfactory participation in a treatment program would to all intents and purposes become unenforceable. Moreover, if it were held to be enforceable, the operative decision on the revocation issue would then be made by the program, arguably exacerbating rather than alleviating its role-conflict problem. It may thus be the part of wisdom to confess that some degree of role-conflict is inherent in the situation of any program which accepts criminal justice referrals. If so, the issue then becomes that of finding the most constructive way to handle the conflict, rather than a sterile and futile effort to avoid it altogether.

(c) We are persuaded that in many instances a prohibition on free communication between probation officers and drug abuse program counsellors would have profoundly deleterious effects on the rehabilitative process. Many probation officers bring to their work a high degree of training, professionalism, and experience. They are under no illusion that they are dealing with a clientele which will never stumble or relapse, and if they have the information necessary to intervene at an early stage of such an episode, their intervention can often make the difference between success and failure for the client.

(d) There is, however, nothing in these regulations which precludes treatment programs from entering into agreements or arrangements with agencies or institutions of the criminal justice system to regulate or restrict the subject matter or form of communications of information about patients. For example, such an arrangement might provide for free oral communication between counsellors and probation officers, while restricting formal written reports by the program to specified types of so-called hard data such as attendance and urinalysis results. In view of widely differing conditions and attitudes in various parts of the country, substantial variations in such arrangements are not only expectable but desirable.

(e) A further aspect of this matter, which was not adequately considered or dealt with in the May 9, proposal, is the impact which the rules laid down in § 2.39 have on the bail decision. There is a high correlation between the disposition of the application for bail and the type of sentence which may be meted out upon conviction. The contrast between the recidivism rates for those who receive treatment and supervision, as against those who simply receive the punishment of incarceration, is a powerful argument against restrictions which would tend to narrow the circumstances under which conscientious judges can grant bail.

(f) It must be emphasized that § 2.39 in no way reduces the necessity to obtain written consent from patients, whether or not referred by the criminal justice system, before disclosures for the purposes here involved can be made by programs. We have been urged to make an exception from the requirement of § 2.31 in the case of parolees and probationers, but such an exception would be wholly unsupported by the authorizing legislation. In fashioning these regulations, it is not our privilege to adorn a tabula rasa according to our own predilections: rather, it is our duty to interlineate a statute with fidelity to its spirit, its terms, and its purposes.

§ 2.40 Situations not otherwise provided for—Rules.

(a) *Criteria for approval.* In any situation not otherwise specifically provided for in this subpart, where consent is given in accordance with § 2.31, a program may make a disclosure for the benefit of a patient from the records of that patient if, in the judgment of the program director or his authorized representative appointed as provided in § 2.17, all of the following criteria are met:

(1) There is no suggestion in the written consent or the circumstances surrounding it, as known to the program, that the consent was not given freely, voluntarily, and without coercion.

(2) Granting the request for disclosure will not cause substantial harm to the relationship between the patient and the program or to the program's capacity to provide services in general.

(3) Granting the request for disclosure will not be harmful to the patient.

(b) *Circumstances deemed beneficial.* For the purposes of this section, the circumstances under which disclosure may be deemed to be beneficial to a patient include, but are not limited to, those in which the disclosure may assist the patient in connection with any public or private claim, right, privilege, gratuity, grant or other interest accruing to, or for the benefit of, the patient or the patient's immediate family. Examples of the foregoing include welfare, medicare, unemployment, workmen's compensation, accident or medical insurance, public or private pension or other retirement benefits, and any claim or defense asserted or which is an issue in any civil, criminal, administrative or other proceeding in which the patient is a party or is affected.

§ 2.40-1 Situations not otherwise provided for—Basis and purpose.

(a) Section 2.40 is based upon § 1401.23 of the previous regulations, amended to reflect the expansion made by the change in the law with respect to the permissible scope of consensual disclosures.

(b) A strong case can be made for the proposition that § 2.40 should, in effect if not expressly, require a program to make any disclosure requested by a patient. The discretion vested in the program, it can be argued, is at best an expression of overprotective paternalism, and at worst, an invitation to programs to cover up material potentially embarrassing to themselves. Bearing in mind, however, that persons who have obtained the type of treatment to which this part applies are more vulnerable to pressures of various kinds than are patients in general, it seems preferable to retain some responsibility on the part of the program to protect the best interests of its patients in this very sensitive area. This, like many other choices which these regulations reflect, is a determination which can be reviewed and revised from time to time in the light of experience.

Subpart D—Disclosures Without Patient Consent

§ 2.51 Medical emergencies—Rules.

(a) *In general.* Disclosure to medical personnel, either private or governmental, is authorized without the consent of the patient when and to the extent necessary to meet a bona fide medical emergency.

(b) *Food and Drug Administration.* Where treatment involves the use of any drug, and appropriate officials of the Food and Drug Administration determine that the life or health of patients may be endangered by an error in the manufacture or packaging of such drug, disclosure of the identities of the recipients of the drug may be made without their consent to appropriate officials of the Food and Drug Administration to enable them to notify the patients or their physicians of the problem in order that corrective action may be taken.

(c) *Incapacitated persons.* Where a patient is incapacitated and information concerning the treatment being given him by a program is necessary to make a sound determination of appropriate emergency treatment, such information may be given without the patient's consent to personnel providing such emergency treatment.

(d) *Notification of family or others.* When any individual suffering from a serious medical condition resulting from drug or alcohol abuse is receiving treatment at a facility which is within the scope of this part the treating physician may, in his discretion, give notification of such condition to a member of the individual's family or any other person with whom the individual is known to have a responsible personal relationship. Such notification may not be made without such individual's consent at any time such individual is capable of rational communication.

(e) *Record required.* Any program making an oral disclosure under authority of this section shall make a written memorandum showing the patient's name or case number, the date and time the disclosure was made, some indication of the nature of the emergency, the information disclosed, and the names of the individuals by whom and to whom it was disclosed.

§ 2.51-1 Medical emergencies—Basis and purpose.

The provisions of § 2.51 are adapted from § 1401.42 of the previous regulations, and are based on subsection (b)(2)(A) of the authorizing legislation. The provision in the previous regulations with respect to patients who may be incarcerated is now covered in § 2.33(b).

Paragraph (d) of § 2.51 is based upon the theory that the disclosure there allowed is of the patient's endangered condition, not his identity as a drug or alcohol abuse patient, and that the humanitarian necessity of such notification outweighs its potential for accidental violation of confidentiality.

§ 2.52 Research, audit, and evaluation—Rules.

(a) *Research, audit, and evaluation.* Subject to any applicable specific provision set forth hereinafter in this subpart, the content of records pertaining to any patient which are maintained in connection with the performance of a function subject to this part may be disclosed, whether or not the patient gives consent, to qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner. For the purposes of this subpart and for the purposes of subsection (b)(2)(B) of the authorizing legislation, the term "qualified personnel" means persons whose training and experience are appropriate to the nature and level of the work in which they are engaged and who, when working as part of an organization, are performing such work with adequate administrative safeguards against unauthorized disclosures.

(b) *Use of disclosures of patient identifying information.* (1) Where a disclosure made to any person pursuant to paragraph (a) of this section includes patient identifying information with respect to any patient, such information may not be further disclosed, and may not be used in connection with any legal, administrative, supervisory, or other action whatsoever with respect to such patient, except as provided in paragraphs (b)(2) and (b)(3) of this section.

(2) The inclusion of patient identifying information in any written or oral communication between a person to whom a disclosure has been made pursuant to paragraph (a) of this section and the program making such disclosure does not constitute the identification of a patient in a report or otherwise in violation of paragraph (a) of this section.

(3) Where a disclosure is made pursuant to paragraph (a) of this section to a person qualified to determine, on the basis of such disclosure, the presence of a substantial risk to the health and well being, whether physical or psychological, of any patient, and, in the judgment of such person, such a risk exists and the situation cannot be dealt with solely by means of communications as described in paragraph (b)(2) of this section without intensifying or prolonging the risk as compared with other means of dealing with it, then the initial disclosure under paragraph (a) of this section and any subsequent disclosure or redisclosure of patient identifying information for the purpose of reducing the risk to the patient involved shall be subject to the provisions of § 2.51.

§ 2.52-1 Research, audit, and evaluation—Basis and purpose.

(a) *General purpose.* Paragraph (a) of this section is adapted directly from subsection (b)(2)(B) of the authorizing legislation. The purpose of each is the same: To facilitate the search for truth, whether in the context of scientific investigation, administrative management, or broad issues of public policy, while at the same time safeguarding the personal privacy of the individuals who are the intended beneficiaries of the process or program under investigation. This subpart in particular, and this part as a whole, are intended to aid in carrying out that purpose.

(b) The succeeding sections of this subpart deal with problems which arise in connection with disclosures made for certain specific purposes which have been interpreted as falling within the general purposes embraced by § 2.52. Those sections will be best understood, however, in the light of some discussion of the underlying premises of the general rule, and its relationship to two other legal concepts: the right of privacy, and the duty to obtain informed consent from research subjects.

(c) *The Right of Privacy.* So far as is relevant to this discussion, we may consider the right of privacy in two aspects. One, a protection against improper governmental activity, is the right to be secure against unreasonable searches and seizures guaranteed by the Fourth Amendment, with some expansion from the penumbras of the Fifth and Sixth Amendments. The protections afforded to patients by the authorizing legislation, not to mention these regulations, go far beyond those which are constitutionally required.

(d) The other aspect of the right of privacy, which has sometimes been described as the right to be left alone, is the notion that an individual has a right not to be hurt by intrusions into his essentially personal concerns, or to have essentially private information exploited for commercial gain, whether or not the intrusion or exploitation is in connection with any possible governmental action against him. The courts have spoken of a right of privacy in a wide variety of contexts, but they have repeatedly and explicitly rejected the notion that anyone has a right to go about his daily affairs encapsulated in an impenetrable bubble of anonymity. The courts have been careful to weigh the competing interests, and the social interest in valid research and evaluation is clearly of sufficient moment to be considered in this process.

(e) In defense of the position that disclosure of patient identifying information even for carefully guarded scientific research should be permitted only on a consensual basis, two dominant lines of argument, somewhat interrelated, have emerged. One is that retrospective studies are of questionable value in any case, and the other is that a sampling technique involving informed consent on the part of the members of the sample can always be used to develop the information sought. Neither line of argument will withstand careful scrutiny.

(f) It is true, of course, that the efficacy of a given therapeutic agent can often best be evaluated by means of a well-designed prospective study in which special recordkeeping procedures, special criteria for patient selection, and an appropriate control have all been established with a view to the purpose of the study. There are, however, many important investigations which simply do not lend themselves to such a format. Sometimes the desirability or even the possibility of a particular study does not suggest itself except in retrospect. Another important consideration is the fact that knowledge that an investigation is going on may influence the behavior of patients, clinicians, or both. Where such knowledge can influence the make-up of a sample, it will normally do so in the direction of favorable outcomes, but to an unknown degree, thus tending to invalidate the results reported.

(g) While the sample technique has its uses, especially with populations that are unmanageably large, it is often less difficult and expensive, and less likely to interfere with the actual conduct and outcomes of treatment or rehabilitation processes, to use the full population under study. Even more important than economy and administrative convenience in carrying out a study, there may be an overriding advantage in terms of eliminating any question as to the validity of the results of the study on the ground of bias in the selection of the sample.

(h) *Informed Consent.* The duty to obtain informed consent is obvious and compelling in situations where an individual is exposed to the possibility of harm, either physical or psychological, as a consequence of medical procedures, research, or similar activities. Where such a situation exists the person conducting the research or medical procedure violates his duty to the subject or patient if he proceeds without obtaining the voluntary informed consent from the individual or his legally authorized representative. Thus, in conducting an activity which places the subject or patient at risk the practitioner may not give precedence to a hidden agenda, even for so lofty a motive as the advancement of knowledge. In this regard, see the Department of Health and Human Services's Protection of Human Subjects Regulations, 45 CFR Part 46. Those regulations are applicable to all Department of Health and Human Services grants and contracts supporting research, development and related activities involving human subjects.

(i) It is apparent that the foregoing rationale for requiring informed consent does not apply to the same degree in situations involving the disclosure of clinical records for research in the form of follow-up or retrospective studies. Under these circumstances the risk to the subject is that some disclosure or misuse of information from which he could be identified might result in embarrassment, lost opportunities, or other forms of psychological or social injury. While that possibility of harm could be reduced by requiring consent to every review of clinical records for research purposes, a similar result can be achieved by the less restrictive method of limiting further disclosure of identifying information by the researcher. Given the applicability of this alternative, equally effective means for protecting a patient or subject from the possibility of a harmful public disclosure, it is unreasonable to insist upon informed consent to every review of clinical records for the purposes of conducting legitimate research, particularly since such insistence could lead to the ultimate absurdity of prohibiting efforts to identify the nature and source of an unknown plague simply because the patients or researcher lacked the clairvoyance to have consent forms signed prior to the onset of the affliction.

(j) In sum, there are restraints on certain means of governmental acquisition of information about individuals which are operative irrespective of how the information is used, and there are restraints on the uses of information which are independent of how or by whom it is acquired, but they do not and should not add up to the proposition that the use of information about a person is either morally or legally the absolute prerogative of that person to determine.

(k) For all of these reasons, the authorizing legislation expressly provides that patient consent is not required with respect to disclosures for research, audit, and evaluation, nor does it prohibit individual patient identification in connection with such disclosures. While it is entirely appropriate to impose safeguards and procedures in connection with these activities, it would be wholly inappropriate to use the rulemaking process to impose an absolute requirement of patient consent with respect to activities which by statute may be conducted without it.

(l) *Classification of activities.* It is clear that Congress intended a balancing of the social interest in the validity of the results of inquiry, on the one hand, with the individual interest in anonymity, on the other, all within the limits set by the legislation and the constitution. With that objective in mind, we may now turn to the various categories of activities which come within the purview of this subpart.

(m) These activities may be classified first, in regard to whether participation is voluntary from the standpoint of the program, and second, as to whether the objective is to ascertain compliance with predetermined standards (examinations as defined in § 2.54, and program evaluation as defined in § 2.11(g)(1)), or to ascertain the validity of a given standard or hypothesis (scientific research, and program evaluation as defined in § 2.11(g)(2)). The application of the foregoing classifications logically results in the creation of four categories of activities. Three of them are specifically dealt with in the succeeding sections of this subpart and need not detain us here; the fourth is discussed below.

(n) *Scientific research and evaluation.* Beyond the bare restatement of the authorizing legislation set forth in § 2.52, these regulations are deliberately silent with respect to purely voluntary scientific research and program evaluation in the sense defined in § 2.11(g)(2). Testimony and written comments received on the August 22, 1974 draft regulations were noteworthy in two respects. First, no instances of abuse on the part of persons acquiring patient identifying information under these circumstances were cited. Second, while there was some well-founded criticism of the attempt in that draft to provide guidelines for determining what is scientific research and who is qualified to do it, no usable alternatives—indeed, almost no alternatives at all—were forthcoming.

(o) In one of the written comments, the writer cautioned against any assumption "that our major remaining problems in drug and alcohol abuse treatment are prevention of illicit diversion and protection of confidentiality," and suggested "that we still have a problem in discovering, testing and evaluating improved treatment techniques. To do this," he continued, "one should place minimal obstacles in the way of bona fide clinical and epidemiologic research!"

(p) The result of leaving the rule as it is in the statute, without attempting to sharpen its outlines or define its terms, will be to leave it for interpretation on a case-by-case basis by those who must apply it in practice: the researchers who seek the information, and the programs which supply it. This does not foreclose the possibility of amending the regulations on the basis of experience if it appears either that clinicians are becoming so cautious that research and evaluation studies are being choked off, or that abuses are occurring in the use of information disclosed. But until a need for more detailed regulation in this area is demonstrated, we think its imposition would do more harm than good.

§ 2.53 Governmental agencies—Rules.

(a) *In general.* Where research, audit, or evaluation functions are performed by or on behalf of a State or Federal governmental agency, the minimum qualifications of personnel performing such functions may be determined by such agency, subject to the provisions of this part, with particular reference to the organizational requirements and limitations on the categories of records subject to review by different categories of personnel.

(b) *Financial and administrative records.* Where program records are reviewed by personnel who lack either the responsibility for, or appropriate training and supervision for, conducting scientific research, determining adherence to treatment standards, or evaluating treatment as such, such review should be confined as far as practicable to administrative and financial records. Under no circumstances should such personnel be shown caseworker or counsellor notes, or similar clinical records. Programs should organize their records so that financial and administrative matters can be reviewed without disclosing clinical information and without disclosing patient identifying information except where necessary for audit verification.

(c) *Scientific research and long-term evaluation studies.* No State and no agency or political subdivision of a State may require, as a condition to funding, licensing, or otherwise, that any program furnish patient identifying information for the purpose of conducting scientific research or long-term evaluation studies unless the recipient of such information is legally required to hold such information in confidence, is prohibited from taking any administrative, investigative, or other action with respect to any individual patient on the basis of such information, and is prohibited from identifying, directly or indirectly, any individual patient in any report of such research or evaluation, or otherwise disclosing patient identities in any manner.

(d) *Opinion and description to be furnished program.* Before any patient identifying information is required to be submitted by a program under the circumstances described in paragraph (c), the program shall be furnished—

(1) An opinion by the attorney general or other chief legal officer of the State to the effect that the conditions specified in paragraph (c) of this section are fulfilled with respect to such program or with respect to all programs in such State similarly situated, and

(2) A description of the administrative procedures and physical limitations on access or other measures to provide for the security of the data, but such description shall not be in such detail as to furnish guidance for wrongful attempts to breach such security.

(e) *Exclusiveness of procedures.* No State or local governmental agency may require any treatment program to furnish patient identifying information to itself or any other recipient except in conformity with this section or § 2.54. No Federal agency may require any treatment program to furnish patient identifying information to itself or any other recipient except in conformity with this section (other than paragraph (d)(1) thereof) or § 2.54.

§ 2.53-1 Governmental agencies—Basis and purpose.

Section 2.53 is an implementation of the authority contained in subsection (g) of the authorizing legislation to provide safeguards and procedures to effectuate the purposes of such legislation. It makes clear that whenever information is required of a program, whether by law or by the terms or conditions of a contract or grant, the procedures and safeguards required under this section are applicable.

§ 2.54 Patient identifying information in connection with examinations—Rules.

(a) *Definitions.* For the purposes of this section—

(1) The term "examination" means any examination to which this section is made applicable by paragraph (b) of this section.

(2) The term "examiner" means any individual or any public or private organization, including any Federal, State, or local governmental agency, which conducts an examination to which this section applies.

(b) *Applicability.* This section applies to any examination of the records of a treatment program which is carried out for the purpose of or as aid to ascertaining the accuracy or adequacy of its financial or other records, or the efficiency or effectiveness of its financial, administrative, or medical management, or its adherence to financial, legal, medical, administrative, or other standards, regardless of whether such examination is called an audit, an evaluation, an inspection, or by any other name.

(c) *Statement required for disclosure of patient identifying information in connection with examination.* No program may make, and no examiner may require, any disclosure of patient identifying information in connection with an examination unless the examiner furnishes to the program a written statement—

(1) That no record of patient identifying information will be made or retained by or on behalf of the examiner in connection with the examination without notice to the program in accordance with paragraph (c)(2) of this section, or

(2) Setting forth the specific purpose for which a record of patient identifying information is being retained by or on behalf of the examiner, the location at which such information will be kept, and the name, official title, address, and telephone number of a responsible individual to whom any inquiries by the program about the disposition of such record should be directed.

(d) *Disposition of record of patient identifying information in connection with examination.* After any record of patient identifying information retained in connection with an examination has served its purpose, or within the time prescribed in paragraph (e) of this section, whichever is earlier, the examiner shall destroy or return to the program all records (including any copies thereof) containing patient identifying information which have been in its possession in connection with such examination.

(e) *Maximum time allowed for disposition.* The action required by paragraph (d) of this section shall be completed—

(1) Except as provided in paragraph (e)(2) of this section not more than two years after the record was acquired by or on behalf of the examiner, or

(2) Where the record is needed in connection with a formal legal proceeding against the program commenced or to be commenced not more than two years after the record was acquired, and written notice to this effect is furnished to the program within two years after the record was acquired, not later than the termination of such proceeding.

(f) *Notice of final disposition.* When an examiner disposes of records as required by paragraph (d) of this section, or not later than the time prescribed by paragraph (e) of this section, whichever is earlier, the examiner shall furnish to the program concerned a written statement—

(1) That there has been compliance with this section and with the provisions of this part prohibiting any disclosure of patient identifying information from records held by auditors or evaluators, or

(2) Specifying the particulars in which there has been a failure of compliance.

§ 2.54-1 Patient identifying information in connection with examinations—Basis and purpose.

Confidence on the part of treatment program personnel in the integrity of auditing and regulatory processes is important to the effective functioning of the treatment system. It is the purpose of § 2.54 to foster practices which will both justify and engender such confidence.

§ 2.55 Supervision and regulation of narcotic maintenance and detoxification programs—Rules.

(a) *Definition of "registrant".* For the purposes of this section, the term "registrant" means a person who (1) has pending an application for registration under section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)), or (2) has been registered under such section and whose registration has not expired or been surrendered or revoked.

(b) *Drug Enforcement Administration.* Duly authorized agents of the Drug Enforcement Administration shall have access to the premises of registrants for the purpose of ascertaining compliance (or ability to comply) with standards established by the Attorney General under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) respecting the security of stocks of narcotic drugs and the maintenance of records (in accordance with section 307 of the Controlled Substances Act, 21 U.S.C. 827) on such drugs. Registrants shall maintain such records separate from and in addition to patients' clinical records required to be maintained under 21 CFR 310.505(d)(7)(iii), which shall not be available to such agents except as authorized under a court order in accordance with Subpart E of this part. Records maintained by registrants for the purposes of section 307 of the Controlled Substances Act (21 U.S.C. 827) need not identify patients by name, address, social security number, or otherwise except by an identifying number assigned by the registrant, but where such a system is used, the registrant shall maintain on a current basis a cross-index referencing each identifying number to the name and address of the patient to whom it refers. Upon request at any time and without advance notice, but subject to the provisions of § 2.54, such agents shall be granted immediate access to any such index. Such agents may use names and addresses so obtained strictly for the purposes of auditing or verifying program records, and shall exercise all reasonable precautions to avoid inadvertent disclosure of patient identities to third parties. Names and other identifying information so obtained may not be compiled or used in any registry or personal data bank of any description.

(c) *Food and Drug Administration.* Duly authorized agents of the Food and Drug Administration shall have access to the premises of registrants and to all records maintained by registrants, for the purpose of ascertaining compliance (or ability to comply) with standards established by the Secretary of Health and Human Services under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 257a), sections 303(g)(1) and 303(g)(3) of the Controlled Substances Act (21 U.S.C. 823(g)(1) and 823(g)(3)), and sections 505 and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 and 371(a)). When necessary in the conduct of their duties, and subject to the provisions of § 2.54, agents may use names and addresses of patients strictly for the purposes of auditing or verifying program records, and shall exercise all reasonable precautions to avoid inadvertent disclosure of patient identities to third parties. Names and other identifying information on patients obtained pursuant to this section or by any other compulsory process may not be compiled or used in any registry or personal data bank of any description. Except as authorized under this paragraph or by a court order granted under Subpart E of this part, (1) such agents may not, either orally or in writing, except in conversation with personnel of the registrant while on the premises of the registrant, identify any patient otherwise than by reference to an identifying number assigned by the registrant, and (2) such agents may not remove from the premises of the registrant any notes, documents, or copies thereof which contain patient identifying information.

(d) *State drug law enforcement agencies.* Duly authorized agents of any State drug law enforcement agency having jurisdiction and specific responsibility by statute or otherwise for the enforcement of criminal laws relating to controlled substances (as defined in the Controlled Substances Act) shall have access to the premises of any registrant for the purposes (with respect to corresponding provisions, if any, of State law) and subject to the restrictions and limitations set forth in paragraph (b) of this section, and subject to § 2.54.

(e) *State health authorities*—(1) *Definition of "qualified State health agency".* As used in this paragraph, the term "qualified State health agency" means an agency of State government (i) which has express legal responsibility to ascertain that registrants under its jurisdiction comply with appropriate treatment standards; (ii) which is legally and administratively separate from any agency of

State government responsible for investigation of violations of, or enforcement of, criminal law generally or criminal laws relating to controlled substances; (iii) whose personnel are qualified by training or experience to conduct inspections of health care facilities to ascertain compliance with treatment standards; and (iv) whose personnel are by State law, or by published administrative directive enforced by effective sanctions, required to maintain the confidentiality of any information concerning the identity of patients which they may acquire in the course of their official duties.

(2) *Access.* Duly authorized agents of a qualified State health agency shall have access to the premises of registrants and to all records maintained by registrants, for the purpose of ascertaining compliance (or ability to comply) with treatment standards (including those relating to quantities of narcotic drugs which may be provided for unsupervised use by individuals in treatment) established under State law. Such access, and the use of any information thereby obtained, shall be subject to the restrictions and limitations set forth in paragraph (c) of this section, and subject to § 2.54.

§ 2.55-1 Supervision and regulation of narcotic maintenance and detoxification programs—Basis and purpose.

(a) Section 2.55 is addressed to the general problem described in the following passage from the legislative history of Pub. L. 93-282:

> A major element of the task of fashioning new regulations pursuant to the express rulemaking authority conferred by this legislation will be to reconcile the sometimes conflicting interests of research, audit, and evaluation with rights of privacy and the confidentiality of the relationship between patient and clinician. Such a reconciliation becomes particularly crucial where the functions of research, audit, or evaluation are conducted by a governmental agency with regulatory powers and responsibility, and the treatment involves the use of a drug such as methadone which is in a research status or which is readily susceptible of misuse or illicit diversion.
>
> Because of the difficulty and complexity of the task, the rulemaking authority is intentionally cast in terms broad enough to permit the limitation of the scope, content, or circumstances of any disclosure under subsection (b), whether (b)(1) or (b)(2), in the light of the necessary purposes for which it is made or required. (Congressional Record, daily edition, May 6, 1974, page H3563).

(b) It has been the consistent interpretation of the Special Action Office for Drug Abuse Prevention that the only provision of the authorizing legislation which permits disclosures to compliance officers, whether of DEA, FDA, or state agencies, is subsection (b)(2)(B). That subsection strictly prohibits any further disclosure of names or other identifying information concerning patients, and the statutory prohibition has been buttressed by provisions of these regulations, notably § 2.54, providing safeguards and procedures to assure that the statutory prohibition is respected.

(c) In testimony and written comment on the August 22, 1974 draft of these regulations, it has been urged that access to patient identifying information by law enforcement personnel, even for the limited purposes allowed by statute and regulation, should be prohibited except pursuant to a court order obtained under 21 U.S.C. 1175(b)(2)(C). We believe that such a prohibition is beyond our power to impose.

(d) Section 307(b) of the Controlled Substances Act (21 U.S.C. 827) provides, in pertinent part, "Every * * * record required under this section * * * shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General." It is a well known principle of statutory construction that amendments and repeals by implication are not favored. In *People v. Newman,* 32 N.Y.2d 379, 345 N.Y.S.2d 502, 298 N.E.2d 651 (1973), cert. denied 414 U.S. 1163, 94 S.Ct. 927, 39L. Ed. 2d 116 (1974), the United States filed *amicus* briefs with the Court of Appeals of New York and with the United States Supreme Court, arguing that section 408 of Pub. L. 92-255 (21 U.S.C. 1175) did not effect an implied amendment or repeal of the provisions of Pub. L. 91-513 (21 U.S.C. 872(c) and 42 U.S.C. 242a(a)) which confer on the Attorney General and the Secretary of Health and Human Services the power to grant the so-called research privilege discussed in § 2.24. This position was expressly adopted by the New York court. We cannot now take the inconsistent position that section 408 of Pub. L. 92-255 did indeed amend by implication section 307 of Pub. L. 91-513, particularly in the face of a contrary contemporaneous administrative interpretation by both the Special Action Office for Drug Abuse Prevention and the Department of Justice. In short, if the right of access and copying conferred on Federal agents by 21 U.S.C. 827 is to be amended to provide that it may only be exercised pursuant to a court order in the case of maintenance and detoxification programs, that is a change which must be wrought by the Congress.

(e) In the case of inspections carried out by health supervisory agencies, we think that denial of access to any documents showing patient identifying information may have a serious adverse effect on the validity of the inspection process. Even if a program keeps its own records in terms of patient-identifying numbers assigned by the program, the patient file may contain—may, indeed, be required to contain—documents signed by the patient or originating outside the program. Where signatures, names, and addresses are all obliterated, it is impossible for the inspector to check the file even for apparent internal consistency. We believe that outright forgery is and will remain a rarity, but the temptation to cover improper or inadequate documentation by "accidental misfilings," may be something else again.

(f) From a legal standpoint, the term "audit" has long comprehended the notion of external verification. In a commercial setting, this means that at least some inventory will actually be counted, at least some receivables will be verified by contacting the customers, and so on. To rule that this crucial aspect of the audit process cannot be carried out with respect to a treatment program until after the auditor goes through the procedure of obtaining a specific court order under subsection (b)(2)(C) would seem to contravene the intent of subsection (b)(2)(B).

(g) In all of this, our decisions must be illuminated by a balanced consideration of the best interests of the patient no less than a desire to foster the implementation of cherished values in society at large. If protection of the patient's right to privacy is achieved by means which seriously impair our ability to protect him from exploitation and malpractice, not to mention the diversion of funds intended for his benefit, it would be a hollow victory indeed. We believe that the procedures and safeguards which these regulations impose on the conduct of audits and evaluations will avoid that result, while affording substantial and meaningful new protection to the confidentiality of patient records.

§ 2.56 Prohibition on disclosure of patient identities from research, audit, or evaluation records—Rules.

Where the content of patients records has been disclosed pursuant to this subpart for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State. This prohibition does not affect the accessibility of the original records under authority of a court order referred to in Subpart E.

§ 2.56-1 Prohibition on disclosure of patient identities from research, audit, or evaluation records—Basis and purpose.

Section 2.56 restates the prohibition on further disclosure which is contained in subsection (b)(2)(B) of the authorizing legislation. The relationship of the provisions authorizing court orders to the provisions authorizing disclosure for research, audit, and evaluation, is dealt with in § 2.62.

Subpart E—Court Orders

§ 2.61 Legal effect of order—Rules.

Subsection (b)(2)(C) of the sections which authorize this part (21 U.S.C. 1175 and 42 U.S.C. 4582) empowers the courts, in appropriate circumstances, to authorize disclosures which would otherwise be prohibited by subsection

(a) of those sections. Subsection (b)(2)(C) operates only as a mechanism for the relief of the duty imposed by subsection (a) and not as an affirmative grant of jurisdiction to authorize or compel disclosures prohibited or privileged by other provisions of law, whether Federal or State. An order or provision of an order based on some other authority, or a subpoena, or other appropriate legal process, is required to compel disclosure. To illustrate, if a person who maintains records subject to this part is merely requested, or is even served with a subpoena, to disclose information contained therein in a manner prohibited in the absence of a court order, he must refuse such a request unless, and until, an order is issued under subsection (b)(2)(C). Such an order would remove the prohibition, but could not, of its own force, require disclosure. If there were no subpoena or other compulsory process, or a subpoena had been issued but had expired or been quashed, the custodian of the records would have discretion as to whether to disclose the information sought unless and until disclosure were ordered by means of appropriate legal or administrative process, the authority for which would have to be found in some source other than subsection (b)(2)(C) of the sections authorizing this part.

§ 2.61-1 Legal effect of order—Basis and purpose.

(a) Section 2.61 is a restatement of the interpretative rules embodied in §§ 1401.61 and 1401.62 of the previous regulations. Both the positioning of the authority to issue court orders in S. 2097 as initially passed by the Senate (92nd Congress, 1st Session, December 2, 1971) and the explicit cross-reference in section 408(a) of Pub. L. 92-255 make clear the congressional intent that section 408(b)(2)(C) operate as a mechanism for the relief of the 408(a), strictures and not as an affirmative grant of jurisdiction to authorize disclosures prohibited by other provisions of law, whether Federal or State.

(b) The amendment made by Pub. L. 93-282 to section 333 of the Alcoholism Act (42 U.S.C. 4582) was enacted with the same language and structure as section 408 in this regard in order to make the interpretative rules set forth in § 2.61 applicable to it.

§ 2.62 Inapplicability to secondary records—Rules.

The authority which subsection (b)(2)(C) of the sections which authorize this part (21 U.S.C. 1175 and 42 U.S.C. 4582) confers on courts to issue orders authorizing the disclosure of records applies only to records referred to in subsection (a) of such sections, that is, the records maintained by treatment or research programs which have patients, and not to secondary records generated by the disclosure of the subsection (a) records to researchers, auditors, or evaluators pursuant to subsection (b)(2)(B).

§ 2.62-1 Inapplicability to secondary records—Basis and purpose.

(a) The interpretative rule set forth in § 2.62 is an essential and basic limitation on the scope of (b)(2)(C) orders. It was part of the original regulations under section 408 of Pub. L. 92-255 published November 17, 1972 (37 FR 24638), and was carried forward unchanged in the amended regulations published December 6, 1973 (38 FR 33748), the special status of which has already been noted in § 2.3. See, also, § 2.61-1.

(b) Although this rule is well supported by the history and technical structure of the legislation, the policy considerations in its favor are even more compelling. In § 2.52-1, we have discussed the urgent necessity for access, even without patient consent, to patient records on the part of qualified personnel engaged in scientific research and evaluation. Where this access includes patient identifying information, as it sometimes must if vital work is to be done, there must not be any question whatsoever about the legal inviolability of its confidential status in the hands of the researcher. Granted, there may occur rare occasions when the original records are for some reason not available, where a (b)(2)(C) order would lie as to the original records, and where there would seem to be some advantage in the administration of justice for such an order to permit disclosure of identifying information by the researcher. But compared to the damage which the mere potentiality for access does to the whole research enterprise, the advantage in terms of ability to deal with rare and anomalous cases seems almost trivial. Even in those cases, denial of access to the party seeking the information leaves him in no worse position than if the research or evaluation, which was certainly not undertaken for his benefit, had never been done at all.

(c) Where the secondary records are generated under the circumstances described in § 2.54, of course, this argument does not apply. In that situation, if preliminary examination suggests that the records may be needed for compliance or other administrative or judicial proceedings, the person conducting the audit or other examination should promptly seek the authority of a court order to copy the original records. The use of secondary records thus generated under authority of a court order would then be limited by the terms and purposes of the order, rather than subsection (b)(2)(B) of the authorizing legislation, and thus the rule set forth in § 2.62 would not apply.

§ 2.63 Limitation to objective data—Rules.

(a) *Limitation to objective data.* Except as provided in paragraph (b) of this section, the scope of an order issued pursuant to this subpart may not extend to communications by a patient to personnel of the program, but shall be limited to the facts or dates of enrollment, discharge, attendance, medication, and similar objective data, and may include only such objective data as is necessary to fulfill the purposes for which the order is issued.

(b) *Exception.* When a patient in litigation offers testimony or other evidence pertaining to the content of his communications with a program, an order under this subpart may authorize the submission of testimony or other evidence by the program or its personnel.

§ 2.63-1 Limitation to objective data—Basis and purpose.

In the three-year period subsequent to the original enactment of 21 U.S.C. 1175, not a single occasion was reported to the Special Action Office for Drug Abuse Prevention on which an attempt was made to secure a (b)(2)(C) order authorizing the disclosure of a confidential communication by a patient to a counsellor or other member of the staff of a treatment program. In all of the comments and testimony received on the draft regulations published August 22, 1974, there was nothing to suggest any circumstances under which a court order authorizing such a disclosure would be either desirable or appropriate. Yet the mere possibility that such an order might be issued is to some a source of anxiety which impairs the effectiveness of treatment. Such an ongoing negative effect clearly outweighs the remote theoretical possibility that some peculiar circumstance might arise in which judicial authorization for such a disclosure might be sought. Accordingly, the limitation imposed by § 2.63 on the scope of (b)(2)(C) orders to preclude that possibility, and hence to eliminate its adverse influence on treatment services, appears to be a proper exercise of rulemaking power.

§ 2.64 Procedures and criteria in general—Rules.

(a) *Identity of patient.* Applications for court orders to authorize disclosure of records pertaining to a known patient shall not use the real name of the patient unless the patient consents thereto voluntarily and intelligently. In the case of an *ex parte* application initiated by the patient, the application should be instituted in the name of a fictitious person, such as Jon Doe, unless the patient requests otherwise. The same procedure should be followed in the case of a separate proceeding held in conjunction with a pending criminal or civil action. Any court order should identify the patient fictitiously, and the disclosure of the patient's real name should be communicated to the program in such manner as to protect the confidentiality of the patient's identity.

(b) *Notice.* In any proceeding not otherwise provided for in this subpart, in which the patient or the program has not been made a party, each shall be given appropriate notice and an opportunity to appear in person or to file a responsive statement, deposition or other form of response consistent with local rules of procedure. The court shall give due consideration to any such statement, deposition or other response in exercising its discretion as to the existence of good cause and, if deemed necessary or desirable, consistent with local rules of procedure, it may order the program director to appear and give direct testimony.

(c) *Hearings.* All hearings and all evidence in connection therewith shall be held or taken in the judge's chambers, unless the patient requests an open hearing or the court determines that such hearing is consistent with the public interest and the proper administration of justice.

(d) *Good cause.* No order shall be issued unless the record shows that good cause exists, and in assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.

(e) *Need for disclosure.* If other competent evidence or sources of information are available, the court should ordinarily deny the application.

(f) *Adverse effects.* If there is evidence that disclosure would have an adverse effect upon successful treatment or rehabilitation of the patient or would impair the effectiveness of the program, or other programs similarly situated, in the treatment or rehabilitation of other patients, the application should be denied unless the court finds that the adverse effects are outweighed by other factors.

(g) *Content of order.* Any order authorizing disclosure shall—

(1) Limit disclosure to those parts of the patient's record deemed essential to fulfill the objective for which the order was granted;

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include any other appropriate measures to keep disclosure to a minimum for the protection of the patient, the physician-patient relationship and the treatment services.

(h) *Applications not otherwise provided for.* In any case not otherwise provided for in this subpart, application for an order authorizing disclosure of records to which this part applies may be made by any person who has a legally cognizable interest in obtaining such disclosure.

§ 2.64-1 Procedures and criteria in general—Basis and purpose.

Section 2.64, in accordance with subsection (g) of the authorizing legislation, sets out procedures and criteria for the issuance of (b)(2)(C) orders in general, subject to the more specific provisions with respect to particular types of proceedings covered in the succeeding sections of this subpart.

§ 2.65 Investigation and prosecution of patients—Rules.

(a) *Applicability.* This section applies to any application by an investigative, law enforcement, or prosecutorial agency for an order to permit disclosure of patient records for the purpose of conducting an investigation or prosecution of an individual who is, or who is believed to be, a present or former patient in a program.

(b) *Notice.* Except where an order under § 2.66 is sought in conjunction with an order under this section, any program with respect to whose records an order is sought under this section shall be notified of the application and afforded an opportunity to appear and be heard thereon.

(c) *Criteria.* A court may authorize disclosure of records pertaining to a patient for the purpose of conducting an investigation of or a prosecution for a crime of which the patient is suspected only if the court finds that all of the following criteria are met:

(1) The crime was extremely serious, such as one involving kidnapping, homicide, assault with a deadly weapon, armed robbery, rape, or other acts causing or directly threatening loss of life or serious bodily injury, or was believed to have been committed on the premises of the program or against personnel of the program.

(2) There is a reasonable likelihood that the records in question will disclose material information or evidence of substantial value in connection with the investigation or prosecution.

(3) There is no other practicable way of obtaining the information or evidence.

(4) The actual or potential injury to the physician-patient relationship in the program affected and in other programs similarly situated, and the actual or potential harm to the ability of such programs to attract and retain patients, is outweighed by the public interest in authorizing the disclosure sought.

(d) *Scope.* Both disclosure and dissemination of any information from the records in question shall be limited under the terms of the order to assure that no information will be unnecessarily disclosed and that dissemination will be no wider than necessary. Under no circumstances may an order under this section authorize a program to turn over patient records in general, pursuant to a subpoena or otherwise, to a grand jury or a law enforcement, investigative, or prosecutorial agency.

(e) *Counsel.* Any application to which this section applies shall be denied unless the court makes an explicit finding to the effect that the program has been afforded the opportunity to be represented by counsel independent of counsel for the applicant, and in the case of any program operated by any department or agency of Federal, State, or local Government, is in fact so represented.

§ 2.65-1 Investigation and prosecution of patients—Basis and purpose.

(a) The need for objective criteria for the issuance of court orders in connection with investigation or prosecution of patients seems particularly pressing. In the absence of such criteria, the assurance of confidentiality otherwise provided for by the authorizing legislation may be felt to be of little value.

(b) It has not been found possible to frame entirely satisfactory rules for the scope of orders under § 2.65, but an illustration may be helpful. Where a witness to a crime is believed capable of identifying a suspect by appearance, and the criteria set forth in § 2.65(c) are met, and the program has photographs of its patients, the witness alone may be permitted to view the photographs, with no names attached. If the witness failed to identify any photograph as being a picture of the suspect, that would end the matter. If there was such an identification, the program would be authorized to give any information in its possession as to the suspect's identity and whereabouts to appropriate authorities.

(c) It is not the purpose of this section to substitute a mechanical formula for judicial discretion, but rather to provide criteria which define the area within which discretion is to be exercised. The reason for including all crimes committed on program premises or against program personnel is not any special solicitude for programs as opposed to other victims of crime, but is rather the result of the special difficulties which the broad definition of "records" in § 2.11(o) creates for program personnel as complaining witnesses.

(d) In regard to § 2.65(e), experience has demonstrated that independent counsel may be of crucial importance. The leading case construing 21 U.S.C. 1175, *People* v. *Newman,* 32 N.Y.2d 379, 345 N.Y.S.2d 502, 298 N.E.2d 651 (1973); certiorari denied, 414 U.S. 1163, 94 S.Ct. 927, 39 L. Ed.2d 116 (1974), would never have been presented to the courts but for the fact that legal counsel for Dr. Newman was furnished on a *pro bono publico* basis by a private law firm. In an entirely different case, a United States District Court appears to have issued a wholly inappropriate order under 21 U.S.C. 1175 in a case in which the treatment program involved was operated by an agency of the United States Government, and either was unrepresented, or was represented by the same attorney who represented the agency seeking the order. It is possible, of course, that the order would have been issued in any event, but it seems clear that there was no adequate presentation to the court of arguments or testimony in opposition. It is difficult to see how the purposes of subsection (b)(2)(C) of the authorizing legislation can be carried out if there is inadequate presentation of the issues to the courts which must decide them.

§ 2.66 Investigation and prosecution of programs—Rules.

(a) *Applicability.* This section applies to any application by an administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency for an order to permit disclosure of patient records or the making of copies thereof (including patient identifying information) for the purpose of conducting an investigation or an administrative or judicial proceeding with respect to any program or any principal, agent, or employee thereof in his capacity as such.

(b) *Notice.* An application under this section may, in the discretion of the court, be granted without notice, but upon the implementation of any order so granted, the program shall be afforded an opportunity to seek the revocation or amendment of such order.

(c) *Scope.* Both disclosure and dissemination of any information from the records in question shall be limited under the terms of the order to assure that patient identities will be protected to the maximum practicable extent, and that names and other identifying characteristics of patients are expunged from any documents placed in any public record. No information obtained pursuant to an order under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.65.

§ 2.66-1 Investigation and prosecution of programs—Basis and purpose.

The principal purpose of § 2.66 is to enable a regulatory agency whose inspection or other source of information has disclosed a need for follow-up, or which has been refused access to patient records, to obtain the necessary authorization for access and copying. There may also be rare instances, such as those involving financial fraud, tax evasion, or other offenses where access by other investigative agencies is necessary, subject to the requirements and protections of this part.

§ 2.67 Undercover agents and informants—Rules.

(a) *Applicability.* This section applies to any application by an administrative, regulatory, supervisory, investigative, or law enforcement agency for an order to permit such agency to have an undercover agent or informant in a program under circumstances which would otherwise be prohibited under § 2.19.

(b) *Notice.* An order under this section may be granted without notice where the criminal conduct for the investigation of which it is granted is believed to be carried on by the program director or by any employee or agent of the program with the knowledge of the program director or under such circumstances that in the exercise of reasonable care the program director should know of such conduct. Under any other circumstances, an order under this section may be granted only after the program director has been afforded notice and opportunity for hearing.

(c) *Criteria.* An order under this section may be granted only where there is reason to believe that a program or any principal, agent, or employee thereof is engaged in serious criminal misconduct, and that other means of securing evidence of such criminal misconduct are not available or would not be effective.

(d) *Scope.* An order granted pursuant to this section may authorize the use by the applicant of an undercover agent or informant, either as a patient or as an employee, of the program in question.

(e) *Time periods.* An order under this section may not authorize the use of an undercover agent for an initial period exceeding 60 days. At any time prior to the expiration of such 60-day period, the applicant may apply for an order extending such period for an additional period not to exceed 60 days, but in no event may the use of an undercover agent in any program be authorized for more than 180 days in any period of 12 consecutive months.

(f) *Duty of agent.* Except to the extent expressly authorized in an order under this section, which shall be limited to disclosure of information directly related to the purpose for which the order is granted, an undercover agent or informant shall for the purposes of this part be deemed an agent of the program within which he is acting as such, and as such shall be subject to all of the prohibitions of this part applicable to disclosures of any information which he may acquire.

§ 2.67-1 Undercover agents and informants—Basis and purpose.

The legal rationale underlying this section has been set forth in § 2.19-1. It is expected that this section will find its principal and perhaps its exclusive application in the area of drug law enforcement. Experience has demonstrated that medical personnel, no matter how credentialed, can engage in the illicit sale of drugs on a large scale, and that the use of undercover agents and informants is normally the only effective means of securing evidence sufficient to support a successful prosecution.

PART 2a—PROTECTION OF IDENTITY—RESEARCH SUBJECTS

Sec.

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AUTHORITY: Sec. 3(a), Pub. L. 91-513 as amended by sec. 122(b), Pub. L. 93-282; 84 Stat. 1241 (42 U.S.C. 242a(a)), as amended by 88 Stat. 132.

SOURCE: 44 FR 20384, Apr. 4, 1979, unless otherwise noted.

§ 2a.1 Applicability.

(a) Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) provides that "[t]he Secretary [of Health and Human Services] may authorize persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals." The regulations in this part establish procedures under which any person engaged in research on mental health including research on the use and effect of alcohol and other psychoactive drugs (whether or not the research is federally funded) may, subject to the exceptions set forth in paragraph (b) of this section, apply for such an authorization of confidentiality.

(b) These regulations do not apply to:

(1) Authorizations of confidentiality for research requiring an Investigational New Drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or to approved new drugs, such as methadone, requiring continuation of long-term studies, records, and reports. Attention is called to 21 CFR 291.505(g) relating to authorizations of confidentiality for patient records maintained by methadone treatment programs.

(2) Authorizations of confidentiality for research which are related to law enforcement activities or otherwise within the purview of the Attorney General's authority to issue authorizations of confidentiality pursuant to section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)) and 21 CFR 1316.21.

(c) The Secretary's regulations on confidentiality of alcohol and drug abuse patient records (42 CFR Part 2) and the regulations of this part may, in some instances, concurrently cover the same transaction. As explained in 42 CFR 2.24 and 2.24-1, 42 CFR Part 2 restricts voluntary disclosures of information from applicable patient records while a Confidentiality Certificate issued pursuant to the regulations of this part protects a person engaged in applicable research from being compelled to disclose identifying characteristics of individuals who are the subject of such research.

§ 2a.2 Definitions.

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(b) "Person" means any individual, corporation, government, or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(c) "Research" means systematic study directed toward new or fuller knowledge and understanding of the subject studied. The term includes, but is not limited to, behavioral science studies, surveys, evaluations, and clinical investigations.

(d) "Drug" has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(e) "Controlled drug" means a drug which is included in schedule I, II, III, IV, or V of Part B of the Controlled Substances Act (21 U.S.C. 811-812).

(f) "Administer" refers to the direct application of a drug to the body of a human research subject, whether such application be by injection, inhalation, ingestion, or any other means, by (1) a qualified person engaged in research (or, in his or her presence, by his or her authorized agent), or (2) a research subject in accordance with instructions of a qualified person engaged in research, whether or not in the presence of a qualified person engaged in research.

(g) "Identifying characteristics" refers to the name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject.

(h) "Psychoactive drug" means, in addition to alcohol, any drug which has as its principal action an effect on thought, mood, or behavior.

§ 2a.3 Application; coordination.

(a) Any person engaged in (or who intends to engage in) the research to which this part applies, who desires authorization to withhold the names and other identifying characteristics of individuals who are the subject of such research from any person or authority not connected with the conduct of such research may apply to the Office of the Director, National Institute on Drug Abuse, the Office of the Director, National Institute of Mental Health, or the Office of the Director, National Institute on Alcohol Abuse and Alcoholism, 5600 Fishers Lane, Rockville, Maryland 20857 for an authorization of confidentiality.

(b) If there is uncertainty with regard to which Institute is appropriate or if the research project falls within the purview of more than one Institute, an application need be submitted only to one Institute. Persons who are uncertain with regard to the applicability of these regulations to a particular type of research may apply for an authorization of confidentiality under the regulations of this part to one of the Institutes. Requests which are within the scope of the authorities described in § 2a.1(b) will be forwarded to the appropriate agency for consideration and the person will be advised accordingly.

(c) An application may accompany, precede, or follow the sumission of a request for DHHS grant or contract assistance, though it is not necessary to request DHHS grant or contract assistance in order to apply for a Confidentiality Certificate. If a person has previously submitted any information required in this part in connection with a DHHS grant or contract, he or she may substitute a copy of information thus submitted, if the information is current and accurate. If a person requests a Confidentiality Certificate at the same time he or she submits an application for DHHS grant or contract assistance, the application for a Confidentiality Certificate may refer to the pertinent section(s) of the DHHS grant or contract application which provide(s) the information required to be submitted under this part. (See §§ 2a.4 and 2a.5.)

(d) A separate application is required for each research project for which an authorization of confidentiality is requested.

§ 2a.4 Contents of application; in general.

In addition to any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project shall contain:

(a) The name and address of the individual primarily responsible for the conduct of the research and the sponsor or institution with which he or she is affiliated, if any. Any application from a person affiliated with an institution will be considered only if it contains or is accompanied by documentation of institutional approval. This documentation may consist of a written statement signed by a responsible official of the institution or of a copy of or reference to a valid certification submitted in accordance with 45 CFR Part 46.

(b) The location of the research project and a description of the facilities available for conducting the research, including the name and address of any hospital, institution, or clinical laboratory facility to be utilized in connection with the research.

(c) The names, addresses, and summaries of the scientific or other appropriate training and experience of all personnel having major responsibilities in the research project and the training and experience requirements for major positions not yet filled.

(d) An outline of the research protocol for the project including a clear and concise statement of the purpose and rationale of the research project and the general research methods to be used.

(e) The date on which research will begin or has begun and the estimated date for completion of the project.

(f) A specific request, signed by the individual primarily responsible for the conduct of the research, for authority to withhold the names and other identifying characteristics of the research subjects and the reasons supporting such request.

(g) An assurance (1) From persons making application for a Confidentiality Certificate for a research project for which DHHS grant or contract support is received or sought that they will comply with all the requirements of 45 CFR Part 46, "Protection of Human Subjects," or

(2) From all other persons making application that they will comply with the informed consent requirements of 45 CFR 46.103(c) and document legally effective informed consent in a manner consistent with the principles stated in 45 CFR 46.110, if it is determined by the Secretary, on the basis of information submitted by the person making application, that subjects will be placed at risk. If a modification of paragraphs (a) or (b) of 45 CFR 46.110 is to be used, as permitted under paragraph (c) of that section, the applicant will describe the proposed modification and submit it for approval by the Secretary.

(h) An assurance that if an authorization of confidentiality is given it will not be represented as an endorsement of the research project by the Secretary or used to coerce individuals to participate in the research project.

(i) An assurance that any person who is authorized by the Secretary to protect the privacy of research subjects will use that authority to refuse to disclose identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects.

(j) An assurance that all research subjects who participate in the project during the period the Confidentiality Certificate is in effect will be informed that:

(1) A Confidentiality Certificate has been issued;

(2) The persons authorized by the Confidentiality Certificate to protect the identity of research subjects may not be compelled to identify research subjects in any civil, criminal, administrative, legislative, or other proceedings whether Federal, State, or local;

(3) If any of the following conditions exist the Confidentiality Certificate does not authorize any person to which it applies to refuse to reveal identifying information concerning research subjects: (i) The subject con-

sents in writing to disclosure of identifying information, (ii) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or regulations promulgated thereunder (Title 21, Code of Federal Regulations), or (iii) Authorized personnel of DHHS request identifying information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See § 2a.7(b));

(4) The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects;

(5) The Confidentiality Certificate does not represent an endorsement of the research project by the Secretary.

(k) An assurance that all research subjects who enter the project after the termination of the Confidentiality Certificate will be informed that the authorization of confidentiality has ended and that the persons authorized to protect the identity of research subjects by the Confidentiality Certificate may not rely on the Certificate to refuse to disclose identifying characteristics of research subjects who were not participants in the project during the period the Certificate was in effect. (See § 2a.8(c)).

§ 2a.5 Contents of application; research projects in which drugs will be administered.

(a) In addition to the information required by § 2a.4 and any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project which involves the administering of a drug shall contain:

(1) Identification of the drugs to be administered in the research project and a description of the methods for such administration, which shall include a statement of the dosages to be administered to the research subjects;

(2) Evidence that individuals who administer drugs are authorized to do so under applicable Federal and State law; and

(3) In the case of a controlled drug, a copy of the Drug Enforcement Administration Certificate of Registration (BND Form 223) under which the research project will be conducted.

(b) An application for an authorization of confidentiality with respect to a research project which involves the administering of a controlled drug may include a request for exemption of persons engaged in the research from State or Federal prosecution for possession, distribution, and dispensing of controlled drugs as authorized under section 502(d) of the Controlled Substances Act (21 U.S.C. 872(d)) and 21 CFR 1316.22. If the request is in such form, and is supported by such information, as is required by 21 CFR 1316.22, the Secretary will forward it, together with his or her recommendation that such request be approved or disapproved, for the consideration of the Administrator of the Drug Enforcement Administration.

§ 2a.6 Issuance of Confidentiality Certificates; single project limitation.

(a) In reviewing the information provided in the application for a Confidentiality Certificate, the Secretary will take into account:

(1) The scientific or other appropriate training and experience of all personnel having major responsibilities in the research project;

(2) Whether the project constitutes bona fide "research" which is within the scope of the regulations of this part; and

(3) Such other factors as he or she may consider necessary and appropriate. All applications for Confidentiality Certificates shall be evaluated by the Secretary through such officers and employees of the Department and such experts or consultants engaged for this purpose as he or she determines to be appropriate.

(b) After consideration and evaluation of an application for an authorization of confidentiality, the Secretary will either issue a Confidentiality Certificate or a letter denying a Confidentiality Certificate, which will set forth the reasons for such denial, or will request additional information from the person making application. The Confidentiality Certificate will include:

(1) The name and address of the person making application;

(2) The name and address of the individual primarily responsible for conducting the research, if such individual is not the person making application;

(3) The location of the research project;

(4) A brief description of the research project;

(5) A statement that the Certificate does not represent an endorsement of the research project by the Secretary;

(6) The Drug Enforcement Administration registration number for the project, if any; and

(7) The date or event upon which the Confidentiality Certificate becomes effective, which shall not be before the later of either the commencement of the research project or the date of issuance of the Certificate, and the date or event upon which the Certificate will expire.

(c) A Confidentiality Certificate is not transferable and is effective only with respect to the names and other identifying characteristics of those individuals who are the subjects of the single research project specified in the Confidentiality Certificate. The recipient of a Confidentiality Certificate shall, within 15 days of any completion or discontinuance of the research project which occurs prior to the expiration date set forth in the Certificate, provide written notification to the Director of the Institute to which application was made. If the recipient determines that the research project will not be completed by the expiration date set forth in the Confidentiality Certificate he or she may submit a written request for an extension of the expiration date which shall include a justification for such extension and a revised estimate of the date for completion of the project. Upon approval of such a request, the Secretary will issue an amended Confidentiality Certificate.

(d) The protection afforded by a Confidentiality Certificate does not extend to significant changes in the research project as it is described in the application for such Certificate (e.g., changes in the personnel having major responsibilities in the research project, major changes in the scope or direction of the research protocol, or changes in the drugs to be administered and the persons who will administer them). The recipient of a Confidentiality Certificate shall notify the Director of the Institute to which application was made of any proposal for such a significant change by submitting an amended application for a Confidentiality Certificate in the same form and manner as an original application. On the basis of such application and other pertinent information the Secretary will either:

(1) Approve the amended application and issue an amended Confidentiality Certificate together with a Notice of Cancellation terminating original the Confidentiality Certificate in accordance with § 2a.8; or

(2) Disapprove the amended application and notify the applicant in writing that adoption of the proposed significant changes will result in the issuance of a Notice of Cancellation terminating the original Confidentiality Certificate in accordance with § 2a.8.

§ 2a.7 Effect of Confidentiality Certificate.

(a) A Confidentiality Certificate authorizes the withholding of the names and other identifying characteristics of individuals who participate as subjects in the research project specified in the Certificate while the Certificate is in effect. The authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information which would identify the subjects of the research. Persons so authorized may not, at any time, be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify the research subjects encompassed by the Certificate, except in those circumstances specified in paragraph (b) of this section.

(b) A Confidentiality Certificate granted under this part does not authorize any person to refuse to reveal the name or other identifying characteristics of any research subject in the following circumstances: (1) The subject (or, if he or she is legally incompetent, his or her guardian) consents, in writing, to the disclosure of such information, (2) Authorized personnel of

DHHS request such information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See 45 CFR 5.71 for confidentiality standards imposed on such DHHS personnel), or (3) Release of such information is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or the regulations promulgated thereunder (Title 21, Code of Federal Regulations).

(c) Neither a Confidentiality Certificate nor the regulations of this part govern the voluntary disclosure of identifying characteristics of research subjects.

§ 2a.8 Termination.

(a) A Confidentiality Certificate is in effect from the date of its issuance until the effective date of its termination. The effective date of termination shall be the earlier of:

(1) The expiration date set forth in the Confidentiality Certificate; or

(2) Ten days from the date of mailing a Notice of Cancellation to the applicant, pursuant to a determination by the Secretary that the research project has been completed or discontinued or that retention of the Confidentiality Certificate is otherwise no longer necessary or desirable.

(b) A Notice of Cancellation shall include: an identification of the Confidentiality Certificate to which it applies; the effective date of its termination; and the grounds for cancellation. Upon receipt of a Notice of Cancellation the applicant shall return the Confidentiality Certificate to the Secretary.

(c) Any termination of a Confidentiality Certificate pursuant to this section is operative only with respect to the names and other identifying characteristics of individuals who begin their participation as research subjects after the effective date of such termination. (See § 2a.4(k) requiring researchers to notify subjects who enter the project after the termination of the Confidentiality Certificate of termination of the Certificate). The protection afforded by a Confidentiality Certificate is permanent with respect to subjects who participated in research during any time the authorization was in effect.

PART 3—NATIONAL CENTER FOR HEALTH STATISTICS; SPECIAL STATISTICAL SERVICES

Sec.
3.1 Authorization for special statistical services.
3.2 Charges for special statistical services.

§ 3.1 Authorization for special statistical services.

Upon the receipt of a written request by any person, firm or corporation the Director of the National Center for Health Statistics may furnish special statistical services if he determines that: (a) The services requested are within the scope of authorized activities of the center, (b) facilities necessary for the performance of the services are available, (c) the performance of such services will not interfere with the performance of the regular duties of the Center, and (d) the data or statistics requested are not confidential.

(Sec. 3, 49 Stat. 293, as amended; 15 U.S.C. 192a, Reorg. Plan No. 2 of 1946, 11 FR 7873, 60 Stat. 1095, Reorg. Plan No. 1 of 1953, 18 FR 2053, 63 Stat. 631; 3 CFR 1943-1948 Comp.)

[27 FR 3739, Apr. 19, 1962]

§ 3.2 Charges for special statistical services.

The Director of the National Center for Health Statistics will establish a charge for each authorized special statistical service which shall be based on the estimated cost of the service. No services will be undertaken prior to the prepayment of the estimated cost or of such portion of the estimated cost as the Director may require. Adjustments in the prepaid charge resulting in a refund to the requesting party or a further billing by the Center may be made at any time during the progress of the services or upon their completion if necessary to reflect the actual cost of the services.

(Sec. 3, 49 Stat. 293, as amended; 15 U.S.C. 192a, Reorg. Plan No. 2 of 1946, 11 FR 7873, 60 Stat. 1095, Reorg. Plan No. 1 of 1953, 18

FR 2053, 63 Stat. 631; 3 CFR 1943-1948 Comp.)

[27 FR 3739, Apr. 19, 1962]

PART 4—NATIONAL LIBRARY OF MEDICINE

Sec.
4.1 Applicability and scope.
4.2 Purpose of the Library.
4.3 Definitions.
4.4 Access to Library facilities and collections.
4.5 Reference, bibliographic, reproduction and consultation services; fees.
4.6 Publications of the Library and information about the Library.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, sec. 382, 70 Stat. 960, as amended; 42 U.S.C. 216, 276.

SOURCE: 36 FR 3894, Mar. 2, 1971, unless otherwise noted.

§ 4.1 Applicability and scope.

(a) The regulations of this part relate to access to the facilities and library collections, including audiovisual materials, of the National Library of Medicine and the availability of its bibliographic, reproduction, reference, and related services. Such services are those functions performed by the Library directly for the benefit of the general public or health sciences professionals as described in section 382(a)(3)-(5) of the Public Health Service Act.

(b) Such services do not include, and the regulations in this part do not apply to:

(1) Except as provided in § 4.5, functions which relate to the Library's internal processing activities, whether by manual, photographic, or electronic means, as required by section 382(a)(1) and (2) of the Act.

(2) The availability of "records" of the Library as defined in, and available in accordance with, rules and procedures set forth in 45 CFR Part 5 and Part 1 of this chapter.

(3) Federal assistance for medical library construction and other purposes authorized by sections 390-398 of the Act (Parts 59a, 61, 63, and 64 of this chapter).

(4) The availability of facilities, collections and related services of Regional Medical Libraries established or maintained by grants authorized by section 397 of the Act (see Part 59a, Subpart C, of this chapter).

§ 4.2 Purpose of the Library.

In order to assist the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and the public health, the National Library of Medicine, established by section 381 of the Public Health Service Act, acquires and maintains library materials, including audiovisual materials, pertinent to medicine; compiles, publishes, and makes available catalogs, indices, and bibliographies of such materials as appropriate; provides reference and other assistance to research, and engages in other activities in furtherance of the Library's overall purpose.

§ 4.3 Definitions.

As used in this part:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Library" means the National Library of Medicine, established by section 381 of the Act (42 U.S.C. 275).

(c) "Director" means the Director of the Library.

(d) "Collections" means all books, periodicals, prints, films, videotapes, recordings, manuscripts, and other resource materials of the Library, including audio and visual materials produced or developed by the National Medical Audiovisual Center located in Atlanta, Ga., but excluding data processing tapes used solely for internal processing activities to generate reference materials. It does not include "records" as that term is defined in 45 CFR 5.5.

(e) "Historical collection" means materials in the collections published or printed prior to 1871, including manuscripts and prints, and the archival film collection of the National Medical Audiovisual Center and other materials of the collections which, because of age, or unique or unusual value, require special handling, storage, or protection for their preservation, as determined by the Director.

(f) "Health sciences professional" means any person engaged in the administration of health activities, the provision of health services, or in research, teaching or education concerned with the advancement of medicine or other sciences related to health or improvement of the public health.

(g) "Regional Medical Library" means a medical library established or maintained as a regional medical library under section 397 of the Act (42 U.S.C. 280b-8).

§ 4.4 Access to Library facilities and collections.

(a) *General.* The Library facilities and collections are available to any person seeking to make use of the collections, subject to such reasonable rules, consistent with the regulations in this part, as the Director may prescribe to assure the most effective use of such resources by health sciences professionals and to protect the collections from misuse or damage.

(b) *Reading rooms.* Public reading rooms are available for obtaining and reading materials from the collections, subject to rules of the Director designed to provide adequate reading space and orderly conditions and procedures for those using the collections.

(c) *Study rooms.* A limited number of study rooms are available for assignment to individuals requiring extensive use of the collections, or other Library resources. Priority shall be given to persons engaged in "special scientific projects" under section 395 of the Act (42 U.S.C. 280b-5), and to health sciences professionals. Applications for use of study rooms shall be addressed to the Director.

(d) *Use of materials from the collections*—(1) *Materials generally.* Except as otherwise provided in this paragraph, materials from the collections are available for use only in facilities provided by the Library for such purposes.

(2) *Audiovisual materials.* Audio and visual materials in the collections are available for loan application setting forth to the Director's satisfaction that the material will be safeguarded from misuse, damage, loss or misappropriation, and will promptly be returned as required after use or upon request of the Library. Applications for such material may be made to the National Medical Audiovisual Center, Atlanta, Ga. 30333.

(3) *Interlibrary loans.* Materials from the collections, or copies thereof, not specified in paragraph (d)(2) of this section, may be made available for use through libraries of public or private agencies or institutions upon application by such libraries setting forth to the Director's satisfaction that the requesting party has exhausted all other reasonably available local or regional library resources (including Regional Medical Libraries) and, when so prescribed, providing satisfactory assurances that the requested material will be safeguarded from misuse, damage, loss or misappropriation, and will be promptly returned to the Library as required after use or upon request of the Library. Libraries served by a Regional Medical Library are encouraged to file such applications through their Regional Medical Library.

(4) *Loans to health sciences professionals.* Except as provided in paragraph (d)(2) of this section, loans of materials, or copies thereof, from the collections may be made directly to health sciences professionals upon application to the Director setting forth to his satisfaction that the requesting individual is geographically isolated, in terms of distance or available transportation, from all medical literature resources likely to contain the desired material, and providing the assurances to the Director required in paragraph (d)(3) of this section.

(5) *Historical collection.* In addition to the rules specified above with respect to availability of the Library's collections generally, materials from the historical collection are available only in accordance with such other rules as the Director may prescribe to assure their maximum preservation and protection. Such materials may also be made available in the form of microfilm and paper print copies, for which reasonable fees may be levied.

(6) *Gifts and restricted materials.* In addition to the rules specified above, materials in the collections, whether acquired by the Library as the result of gift or purchase, shall be made available only in accordance with limi-

tations imposed as a condition of such gift or purchase.

§ 4.5 Reference, bibliographic, reproduction and consultation services; fees.

(a) *General.* Reference, bibliographic, reproduction (in addition to those reproduction services discussed in § 4.4(d)) and consultation services provided by the Library, whether provided by professional medical librarians, through the use of computerized systems, or otherwise, are available upon request to the extent Library resources permit. In the provisions of services not reasonably available through local or regional library resources, priority shall be given to health sciences professionals.

(b) *Specialized bibliographic services.* (1) Requests for bibliographies on individually selected medical or scientific topics may be filled by use of a reference retrieval system, upon determination by the Director, on the basis of information submitted with the request, that use of such system would be appropriate and effective in the circumstances. Requests must be made upon such forms and in such manner as the Director may from time to time prescribe. Searches determined by the Director to be of general interest may be published and made available for general distribution by the Library.

(2) A limited number of computerized bibilographies on topics of general interest to group users, such as public or nonprofit health related professional societies and research organizations, may be produced on a regularly recurring basis pursuant to contractual arrangements between the Library and public or nonprofit agencies, when determined in each case by the Director to be necessary to assure more effective distribution of the bibliographic information involved, in furtherance of the Library's special purposes.

(c) *MEDLARS tapes.* To the extent Library resources permit, where deemed necessary by the Director to further the dissemination of scientific and other information important to the progress of medicine and the public health, or to assist research and investigations in the field of medical library science, copies of all or part of the Library's magnetic tapes comprising the Medical Literature Analysis and Retrieval System (MEDLARS) may be made available to agencies, organizations and institutions upon application by such persons providing assurances that (1) such tapes will be utilized to provide reference or bibliographic services pertinent to medicine not otherwise available from the Library or a Regional Medical Library, or (2) such tapes are necessary to carry out such research or investigation. The use of such tapes shall be subject to such further conditions as the Director may prescribe when in his judgment necessary to further the purpose of the Library.

(d) *Fees for services.* The Director may, in accordance with schedules available at the Library on request, charge fees reasonably designed to recover all or a portion of the cost to the Library, including the employment of personnel, of providing any of the above or other reference, bibliographic and reproduction services. Such fees shall be charged only where the nature of the service in question is beyond that normally provided to the general public or health sciences professionals or where Library resources are limited or unduly taxed.

§ 4.6 Publications of the Library and information about the Library.

Lists of bibliographies or Library publications sold by the Government Printing Office, and other information concerning the organization, operation, functions and services of the Library, including necessary application forms, are available from the National Library of Medicine, Bethesda, Md. 20014.

PART 5—DESIGNATION OF HEALTH MANPOWER SHORTAGE AREAS

Sec.
5.1 Purpose.
5.2 Definitions.
5.3 Procedures for designation of health manpower shortage areas.
5.4 Notification and publication of designations and withdrawals.
APPENDIX A—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PRIMARY MEDICAL CARE MANPOWER

APPENDIX B—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF DENTAL MANPOWER

APPENDIX C—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PSYCHIATRIC MANPOWER

APPENDIX D—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VISION CARE MANPOWER

APPENDIX E—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PODIATRIC MANPOWER

APPENDIX F—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PHARMACY MANPOWER

APPENDIX G—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VETERINARY MANPOWER

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); sec. 332 of the Public Health Service Act, 90 Stat. 2770-2772 (42 U.S.C. 254e).

SOURCE: 45 FR 76000, Nov. 17, 1980, unless otherwise noted.

§ 5.1 Purpose.

These regulations establish criteria and procedures for the designation of geographic areas, population groups, medical facilities, and other public facilities, in the States, as health manpower shortage areas.

§ 5.2 Definitions.

"Act" means the Public Health Service Act, as amended.

"Health manpower shortage area" means any of the following which the Secretary determines has a shortage of health manpower: (1) An urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services); (2) a population group; or (3) a public or nonprofit private medical facility.

"Health service area" means a health service area whose boundaries have been designated by the Secretary, under section 1511 of the Act, for purposes of health planning activities.

"Health systems agency" or "HSA" means the health systems agency designated, under section 1515 of the Act, to carry out health planning activities for a specific health service area.

"Medical facility" means a facility for the delivery of health services and includes: (1) A community health center, public health center, outpatient medical facility, or community mental health center; (2) a hospital, State mental hospital, facility for long-term care, or rehabilitation facility; (3) a migrant health center or an Indian Health service facility; (4) a facility for delivery of health services to inmates in a U.S. penal or correctional institution (under section 323 of the Act) or a State correctional institution; (5) a Public Health Service medical facility (used in connection with the delivery of health services under section 320, 321, 322, 324, 325, or 326 of the Act); or (6) any other Federal medical facility.

"Metropolitan area" means an area which has been designated by the Office of Management and Budget as a standard metropolitan statistical area (SMSA). All other areas are "nonmetropolitan areas."

"Poverty level" means the poverty level as defined by the Bureau of the Census, using the poverty index adopted by a Federal Interagency Committee in 1969, and updated each year to reflect changes in the Consumer Price Index.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department to whom the authority involved has been delegated.

"State" includes, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

"State health planning and development agency" or "SHPDA" means a State health planning and development agency designated under section 1521 of the Act.

§ 5.3 Procedures for designation of health manpower shortage areas.

(a) Using data available to the Department from national, State, and local sources and based upon the criteria in the appendices to this part, the Department will annually prepare listings (by State and health service area) of currently designated health manpower shortage areas and potentially designatable areas, together with appropriate related data available to the Department. Relevant portions of this material will then be forwarded to each health systems agency, State health planning and development agency, and Governor, who will be asked to review the listings for their State, correct any errors of which they are aware, and offer their recommendations, if any, within 90 days, as to which geographic areas, population groups, and facilities in areas under their jurisdiction should be designated. An information copy of these listings will also be made available, upon request, to interested parties for their use in providing comments or recommendations to the Secretary and/or to the appropriate HSA, SHPDA, or Governor.

(b) In addition, any agency or individual may request the Secretary to designate (or withdraw the designation of) a particular geographic area, population group, or facility as a health manpower shortage area. Each request will be forwarded by the Secretary to the appropriate HSA, SHPDA, and Governor, who will be asked to review it and offer their recommendations, if any, within 30 days. An information copy will also be made available to other interested parties, upon request, for their use in providing comments or recommendations to the Secretary and/or to the appropriate HSA, SHPDA, or Governor.

(c) In each case where the designation of a public facility (including a Federal medical facility) is under consideration, the Secretary will give written notice of the proposed designation to the chief administrative officer of the facility, who will be asked to review it and offer their recommendations, if any, within 30 days.

(d) After review of the available information and consideration of the comments and recommendations submitted, the Secretary will designate health manpower shortage areas and withdraw the designation of any areas which have been determined no longer to have a shortage of health manpower.

§ 5.4 Notification and publication of designations and withdrawals.

(a) The Secretary will give written notice of the designation (or withdrawal of designation) of a health manpower shortage area, not later than 60 days from the date of the designation (or withdrawal of designation), to:

(1) The Governor of each State in which the area, population group, medical facility, or other public facility so designated is in whole or in part located;

(2) Each HSA for a health service area which includes all or any part of the area, population group, medical facility, or other public facility so designated;

(3) The SHPDA for each State in which the area, population group, medical facility, or other public facility so designated is in whole or in part located; and

(4) Appropriate public or nonprofit private entities which are located in or which have a demonstrated interest in the area so designated.

(b) The Secretary will periodically publish updated lists of designated health manpower shortage areas in the FEDERAL REGISTER, by type of manpower shortage. An updated list of areas for each type of manpower shortage will be published at least once annually.

(c) The effective date of the designation of an area shall be the date of the notification letter to the individual or agency which requested the designation, or the date of publication in the FEDERAL REGISTER, whichever comes first.

(d) Once an area is listed in the FEDERAL REGISTER as a designated health manpower shortage area, the effective date of any later withdrawal of the area's designation shall be the date when notification of the withdrawal, or an updated list of designated areas which does not include it, is published in the FEDERAL REGISTER.

APPENDIX A—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PRIMARY MEDICAL CARE MANPOWER

Part I—Geographic Areas

A. *Criteria.*

A geographic area will be designated as having a shortage of primary medical care manpower if the following three criteria are met:

1. The area is a rational area for the delivery of primary medical care services.

2. One of the following conditions prevails within the area:

(a) The area has a population to full-time-equivalent primary care physician ratio of at least 3,500 : 1.

(b) The area has a population to full-time-equivalent primary care physician ratio of less than 3,500 : 1 but greater than 3,000 : 1 and has unusually high needs for primary care services or insufficient capacity of existing primary care providers.

3. Primary medical care manpower in contiguous areas are overutilized, excessively distant, or inaccessible to the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Primary Medical Care Services.*

(a) The following areas will be considered rational areas for the delivery of primary medical care services:

(i) A county, or a group of contiguous counties whose population centers are within 30 minutes travel time of each other.

(ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market or transportation patterns, distinctive population characteristics or other factors, has limited access to contiguous area resources, as measured generally by a travel time greater than 30 minutes to such resources.

(iii) Established neighborhoods and communities within metropolitan areas which display a strong self-identity (as indicated by a homogeneous socioeconomic or demographic structure and/or a tradition of interaction or interdependency), have limited interaction with contiguous areas, and which, in general, have a minimum population of 20,000.

(b) The following distances will be used as guidelines in determining distances corresponding to 30 minutes travel time:

(i) Under normal conditions with primary roads available: 20 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 15 miles.

(iii) In flat terrain or in areas connected by interstate highways: 25 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 30 minutes travel time.

2. *Population Count.*

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions, with the following adjustments, where appropriate:

(a) Adjustments to the population for the differing health service requirements of various age-sex population groups will be computed using the table below of visit rates for 12 age-sex population cohorts. The total expected visit rate will first be obtained by multiplying each of the 12 visit rates in the table by the size of the area population within that particular age-sex cohort and adding the resultant 12 visit figures together. This total expected visit rate will then be divided by the U.S. average per capita visit rate of 5.1, to obtain the adjusted population for the area.

Sex	Age groups					
	Under 5	5-14	15-24	25-44	45-64	65 and over
Male	7.3	3.6	3.3	3.6	4.7	6.4
Female	6.4	3.2	5.5	6.4	6.5	6.8

(b) The effect of transient populations on the need of an area for primary care manpower will be taken into account as follows:

(i) Seasonal residents, i.e., those who maintain a residence in the area but inhabit it for only 2 to 8 months per year, may be included but must be weighted in proportion to the fraction of the year they are present in the area.

(ii) Other tourists (non-resident) may be included in an area's population but only with a weight of 0.25, using the following formula: Effective tourist contribution to population = 0.25 × (fraction of year tourists are present in area) × (average daily number of tourists during portion of year that tourists are present).

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(iii) Migratory workers and their families may be included in an area's population, using the following formula: Effective migrant contribution to population=(fraction of year migrants are present in area)×(average daily number of migrants during portion of year that migrants are present).

3. *Counting of Primary Care Practitioners.*

(a) All non-Federal doctors of medicine (M.D.) and doctors of osteopathy (D.O.) providing direct patient care who practice principally in one of the four primary care specialities—general or family practice, general internal medicine, pediatrics, and obstetrics and gynecology—will be counted. Those physicians engaged solely in administration, research, and teaching will be excluded. Adjustments for the following factors will be made in computing the number of full-time-equivalent (FTE) primary care physicians:

(i) Interns and residents will be counted as 0.1 full-time equivalent (FTE) physicians.

(ii) Graduates of foreign medical schools who are not citizens or lawful permanent residents of the United States will be excluded from physician counts.

(iii) Those graduates of foreign medical schools who are citizens or lawful permanent residents of the United States, but do not have unrestricted licenses to practice medicine, will be counted as 0.5 FTE physicians.

(b) Practitioners who are semi-retired, who operate a reduced practice due to infirmity or other limiting conditions, or who provide patient care services to the residents of the area only on a part-time basis will be discounted through the use of full-time equivalency figures. A 40-hour work week will be used as the standard for determining full-time equivalents in these cases. For practitioners working less than a 40-hour week, every four (4) hours (or ½ day) spent providing patient care, in either ambulatory or inpatient settings, will be counted as 0.1 FTE (with numbers obtained for FTE's rounded to the nearest 0.1 FTE), and each physician providing patient care 40 or more hours a week will be counted as 1.0 FTE physician. (For cases where data are available only for the number of hours providing patient care in office settings, equivalencies will be provided in guidelines.)

(c) In some cases, physicians located within an area may not be accessible to the population of the area under consideration. Allowances for physicians with restricted practices can be made, on a case-by-case basis. However, where only a portion of the population of the area cannot access existing primary care resources in the area, a population group designation may be more appropriate (see Part II of this Appendix).

(d) Hospital staff physicians involved exclusively in inpatient care will be excluded. The number of full-time equivalent physicians practicing in organized outpatient departments and primary care clinics will be included, but those in emergency rooms will be excluded.

(e) Physicians who are suspended under provisions of the Medicare-Medicaid Anti-Fraud and Abuse Act for a period of eighteen months or more will be excluded.

4. *Determination of Unusually High Needs for Primary Medical Care Services.*

An area will be considered as having unusually high needs for primary health care services if at least one of the following criteria is met:

(a) The area has more than 100 births per year per 1,000 women aged 15-44.

(b) The area has more than 20 infant deaths per 1,000 live births.

(c) More than 20% of the population (or of all households) have incomes below the poverty level.

5. *Determination of Insufficient Capacity of Existing Primary Care Providers.*

An area's existing primary care providers will be considered to have insufficient capacity if at least two of the following criteria are met:

(a) More than 8,000 office or outpatient visits per year per FTE primary care physician serving the area.

(b) Unusually long waits for appointments for routine medical services (i.e., more than 7 days for established patients and 14 days for new patients).

(c) Excessive average waiting time at primary care providers (longer than one hour where patients have appointments or two hours where patients are treated on a first-come, first-served basis).

(d) Evidence of excessive use of emergency room facilities for routine primary care.

(e) A substantial proportion (2/3 or more) of the area's physicians do not accept new patients.

(f) Abnormally low utilization of health services, as indicated by an average of 2.0 or less office visits per year on the part of the area's population.

6. *Contiguous Area Considerations.*

Primary care manpower in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Primary care manpower in the contiguous area are more than 30 minutes travel time from the population center(s) of the area being considered for designation (measured in accordance with paragraph B.1(b) of this Part).

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(b) The contiguous area population-to-full-time-equivalent primary care physician ratio is in excess of 2000:1, indicating that practitioners in the contiguous area cannot be expected to help alleviate the shortage situation in the area being considered for designation.

(c) Primary care manpower in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers, such as:

(i) Significant differences between the demographic (or socio-economic) characteristics of the area under consideration and those of the contiguous area, indicating that the population of the area under consideration may be effectively isolated from nearby resources. This isolation could be indicated, for example, by an unusually high proportion of non-English-speaking persons.

(ii) A lack of economic access to contiguous area resources, as indicated particularly where a very high proportion of the population of the area under consideration is poor (i.e., where more than 20 percent of the population or the households have incomes below the poverty level), and Medicaid-covered or public primary care services are not available in the contiguous area.

C. *Determination of Degree of Shortage.*

Designated areas will be assigned to degree-of-shortage groups, based on the ratio (R) of population to number of full-time equivalent primary care physicians and the presence or absence of unusually high needs for primary health care services, according to the following table:

	High needs not indicated	High needs indicated
Group 1	No physicians	No physicians; or R ≥ 5,000
Group 2	R ≥ 5,000	5,000 > R ≥ 4,000
Group 3	5,000 > R ≥ 4,000	4,000 > R ≥ 3,500
Group 4	4,000 > R ≥ 3,500	3,500 > R ≥ 3,000

Part II—Population Groups

A. *Criteria.*

1. In general, specific population groups within particular geographic areas will be designated as having a shortage of primary medical care manpower if the following three criteria are met:

(a) The area in which they reside is rational for the delivery of primary medical care services, as defined in paragraph B.1 of Part I of this Appendix.

(b) Access barriers prevent the population group from use of the area's primary medical care providers. Such barriers may be economic, linguistic, cultural, or architectural, or could involve refusal of some providers to accept certain types of patients or to accept Medicaid reimbursement.

(c) The ratio of the number of persons in the population group to the number of primary care physicians practicing in the area and serving the population group is at least 3,000 : 1.

2. Indians and Alaska Natives will be considered for designation as having shortages of primary care manpower as follows:

(a) Groups of members of Indian tribes (as defined in section 4(d) of Pub. L. 94-437, the Indian Health Care Improvement Act of 1976) are automatically designated.

(b) Other groups of Indians or Alaska Natives (as defined in section 4(c) of Pub. L. 94-437) will be designated if the general criteria in paragraph A are met.

B. *Determination of Degree of Shortage.*

Each designated population group will be assigned to a degree-of-shortage group, based on the ratio (R) of the group's population to the number of primary care physicians serving it, as follows:

Group 1—No physicians or R>5,000.
Group 2—5,000>R>4,000.
Group 3—4,000>R>3,500.
Group 4—3,500>R>3,000.

Population groups which have received "automatic" designation will be assigned to degree-of-shortage group 4 if no information on the ratio of the number of persons in the group to the number of FTE primary care physicians serving them is provided.

Part III—Facilities

A. *Federal and State Correctional Institutions.*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of primary medical care manpower if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE primary care physicians serving the institution is at least 1,000:1. (Here the number of internees is the number of inmates present at the beginning of the year plus the number of new inmates entering the institution during the year, including those who left before the end of the year; the number of FTE primary care physicians is computed as in Part I, Section B, paragraph 3 above.)

2. *Determination of Degree of Shortage.*

Designated correctional institutions will be assigned to degree-of-shortage groups based on the number of inmates and/or the ratio (R) of internees to primary care physicians, as follows:

Group 1—Institutions with 500 or more inmates and no physicians.

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Group 2—Other institutions with no physicians and institutions with $R > 2,000$.

Group 3—Institutions with $2,000 > R > 1,000$.

B. *Public or Non-Profit Medical Facilities.*

1. *Criteria.*

Public or non-profit private medical facilities will be designated as having a shortage of primary medical care manpower if:

(a) the facility is providing primary medical care services to an area or population group designated as having a primary care manpower shortage; and

(b) the facility has insufficient capacity to meet the primary care needs of that area or population group.

2. *Methodology*

In determining whether public or non-profit private medical facilities meet the criteria established by paragraph B.1 of this Part, the following methodology will be used:

(a) *Provision of Services to a Designated Area or Population Group.*

A facility will be considered to be providing services to a designated area or population group if either:

(i) A majority of the facility's primary care services are being provided to residents of designated primary care manpower shortage areas or to population groups designated as having a shortage of primary care manpower; or

(ii) The population within a designated primary care shortage area or population group has reasonable access to primary care services provided at the facility. Reasonable access will be assumed if the area within which the population resides lies within 30 minutes travel time of the facility and non-physical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

Migrant health centers (as defined in section 319(a)(1) of the Act) which are located in areas with designated migrant population groups and Indian Health Service facilities are assumed to be meeting this requirement.

(b) *Insufficient capacity to meet primary care needs.*

A facility will be considered to have insufficient capacity to meet the primary care needs of the area or population it serves if at least two of the following conditions exist at the facility:

(i) There are more than 8,000 outpatient visits per year per FTE primary care physician on the staff of the facility. (Here the number of FTE primary care physicians is computed as in Part I, Section B, paragraph 3 above.)

(ii) There is excessive usage of emergency room facilities for routine primary care.

(iii) Waiting time for appointments is more than 7 days for established patients or more than 14 days for new patients, for routine health services.

(iv) Waiting time at the facility is longer than 1 hour where patients have appointments or 2 hours where patients are treated on a first-come, first-served basis.

3. *Determination of Degree of Shortage.*

Each designated medical facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

APPENDIX B—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF DENTAL MANPOWER

Part I—Geographic Areas

A. *Criteria.*

A geographic area will be designated as having a dental manpower shortage if the following three criteria are met:

1. The area is a rational area for the delivery of dental services.

2. One of the following conditions prevails in the area:

(a) The area has a population to full-time-equivalent dentist ratio of at least 5,000:1, or

(b) The area has a population to full-time-equivalent dentist ratio of less than 5,000:1 but greater than 4,000:1 and has unusually high needs for dental services or insufficient capacity of existing dental providers.

3. Dental manpower in contiguous areas are overutilized, excessively distant, or inaccessible to the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this Part, the following methodology will be used:

1. *Rational Area for the Delivery of Dental Services.*

(a) The following areas will be considered rational areas for the delivery of dental health services:

(i) A county, or a group of several contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county (or an area made up of portions of more than one county) whose population, because of topography, market or transportation patterns, distinctive population characteristics, or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to such resources.

(iii) Established neighborhoods and communities within metropolitan areas which display a strong self-identity (as indicated by a homogenous socioeconomic or demographic structure and/or a traditional of interaction or intradependency), have limited interaction with contiguous areas, and

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which, in general, have a minimum population of 20,000.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

2. *Population Count.*

The population count use will be the total permanent resident civilian population of the area, excluding inmates of institutions, with the following adjustments:

(a) Seasonal residents, i.e., those who maintain a residence in the area but inhabit it for only 2 to 8 months per year, may be included but must be weighted in proportion to the fraction of the year they are present in the area.

(b) Migratory workers and their families may be included in an area's population using the following formula: Effective migrant contribution to population=(fraction of year migrants are present in area)×(average daily number of migrants during portion of year that migrants are present).

3. *Counting of Dental Practitioners.*

(a) All non-Federal dentists providing patient care will be counted, except in those areas where it is shown that specialists (those dentists not in general practice or pedodontics) are serving a larger area and are not addressing the general dental care needs of the area under consideration.

(b) Full-time equivalent (FTE) figures will be used to reflect productivity differences among dental practices based on the age of the dentists, the number of auxiliaries employed, and the number of hours worked per week. In general, the number of FTE dentists will be computed using weights obtained from the matrix in Table 1, which is based on the productivity of dentists at various ages, with different numbers of auxiliaries, as compared with the average productivity of all dentists. For the purposes of these determinations, an auxiliary is defined as any non-dentist staff employed by the dentist to assist in operation of the practice.

Table 1. Equivalency Weights, by Age and Number of Auxiliaries

	<55	55-59	60-64	65+
No auxiliaries	0.8	0.7	0.6	0.5
One auxiliary	1.0	0.9	0.8	0.7
Two auxiliaries	1.2	1.0	1.0	0.8
Three auxiliaries	1.4	1.2	1.0	1.0
Four or more auxiliaries	1.5	1.5	1.3	1.2

If information on the number of auxiliaries employed by the dentist is not available, Table 2 will be used to compute the number of full-time equivalent dentists.

Table 2. Equivalency Weights, by Age

	55	55-59	60-64	65+
Equivalency weights	1.2	0.9	0.8	0.6

The number of FTE dentists within a particular age group (or age/auxiliary group) will be obtained by multiplying the number of dentists within that group by its corresponding equivalency weight. The total supply of FTE dentists within an area is then computed as the sum of those dentists within each age (or age/auxiliary) group.

(c) The equivalency weights specified in tables 1 and 2 assume that dentists within a particular group are working full-time (40 hours per week). Where appropriate data are available, adjusted equivalency figures for dentists who are semi-retired, who operate a reduced practice due to infirmity or other limiting conditions, or who are available to the population of an area only on a part-time basis will be used to reflect the reduced availability of these dentists. In computing these equivalency figures, every 4 hours (or ½ day) spent in the dental practice will be counted as 0.1 FTE except that each dentist working more than 40 hours a week will be counted as 1.0. The count obtained for a particular age group of dentists will then be multiplied by the appropriate equivalency weight from table 1 or 2 to obtain a full-time equivalent figure for dentists within that particular age or age/auxiliary category.

4. *Determination of Unusually High Needs for Dental Services.*

An area will be considered as having unusually high needs for dental services if at least one of the following criteria is met:

(a) More than 20% of the population (or of all households) has incomes below the poverty level.

(b) The majority of the area's population does not have a fluoridated water supply.

5. *Determination of Insufficient Capacity of Existing Dental Care Providers.*

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An area's existing dental care providers will be considered to have insufficient capacity if at least two of the following criteria are met:

(a) More than 5,000 visits per year per FTE dentist serving the area.

(b) Unusually long waits for appointments for routine dental services (i.e., more than 6 weeks).

(c) A substantial proportion (⅓ or more) of the area's dentists do not accept new patients.

6. *Contiguous Area Considerations.*

Dental manpower in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Dental manpower in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation (measured in accordance with Paragraph B.1.(b) of this Part).

(b) Contiguous area population-to-(FTE) dentist ratios are in excess of 3,000 : 1, indicating that resources in contiguous areas cannot be expected to help alleviate the shortage situation in the area being considered for designation.

(c) Dental manpower in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers, such as:

(i) Significant differences between the demographic (or socioeconomic) characteristics of the area under consideration and those of the contiguous area, indicating that the population of the area under consideration may be effectively isolated from nearby resources. Such isolation could be indicated, for example, by an unusually high proportion of non-English-speaking persons.

(ii) A lack of economic access to contiguous area resources, particularly where a very high proportion of the population of the area under consideration is poor (i.e., where more than 20 percent of the population or of the households have incomes below the poverty level) and Medicaid-covered or public dental services are not available in the contiguous area.

C. *Determination of Degree of Shortage.*

The degree of shortage of a given geographic area, designated as having a shortage of dental manpower, will be determined using the following procedure:

Designated areas will be assigned to degree-of-shortage groups, based on the ratio (R) of population to number of full-time-equivalent dentists and the presence or absence of unusually high needs for dental services, or insufficient capacity of existing dental care providers according to the following table:

	High needs or insufficient capacity not indicated	High needs or insufficient capacity indicated
Group 1	No dentists	No dentists or R ≥ 8,000
Group 2	R ≥ 8,000	8,000 > R ≥ 6,000
Group 3	8,000 > R ≥ 6,000	6,000 > R ≥ 5,000
Group 4	6,000 > R ≥ 5,000	5,000 > R ≥ 4,000

Part II—Population Groups

A. *Criteria.*

1. In general, specified population groups within particular geographic areas will be designated as having a shortage of dental care manpower if the following three criteria are met:

a. The area in which they reside is rational for the delivery of dental care services, as defined in paragraph B.1 of Part I of this appendix.

b. Access barriers prevent the population group from use of the area's dental providers.

c. The ratio (R) of the number of persons in the population group to the number of dentists practicing in the area and serving the population group is at least 4,000:1.

2. Indians and Alaska Natives will be considered for designation as having shortages of dental manpower as follows:

(a) Groups of members of Indian tribes (as defined in section 4(d) of Pub. L. 94-437, the Indian Health Care Improvement Act of 1976) are automatically designated.

(b) Other groups of Indians or Alaska Natives (as defined in section 4(c) of Pub. L. 94-437) will be designated if the general criteria in paragraph 1 are met.

B. *Determination of Degree of Shortage.*

Each designated population group will be assigned to a degree-of-shortage group as follows:

Group 1—No dentists or R ≥ 8,000.
Group 2—8,000 > R ≥ 6,000.
Group 3—6,000 > R ≥ 5,000.
Group 4—5,000 > R ≥ 4,000.

Population groups which have received "automatic" designation will be assigned to degree-of-shortage group 4 unless information on the ratio of the number of persons in the group to the number of FTE dentists serving them is provided.

Part III—Facilities

A. *Federal and State Correctional Institutions.*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as

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having a shortage of dental manpower if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE dentists serving the institution is at least 1,500:1. (Here the number of internees is the number of inmates present at the beginning of the year plus the number of new inmates entering the institution during the year, including those who left before the end of the year; the number of FTE dentists is computed as in Part I, Section B, paragraph 3 above.)

2. *Determination of Degree-of-Shortage.*

Designated correctional institutions will be assigned to degree-of-shortage groups as follows, based on number of inmates and/or the ratio (R) of internees to dentists:

Group 1—Institutions with 500 or more inmates and no dentists.

Group 2—Other institutions with no dentists and institutions with $R > 3{,}000$.

Group 3—Institutions with $3{,}000 > R > 1{,}500$.

B. *Public or Non-Profit Private Dental Facilities.*

1. *Criteria.*

Public or nonprofit private facilties providing general dental care services will be designated as having a shortage of dental manpower if both of the following criteria are met:

(a) The facility is providing general dental care services to an area or population group designated as having a dental manpower shortage; and

(b) The facility has insufficent capacity to meet the dental care needs of that area or population group.

2. *Methodology.*

In determining whether public or nonprofit private facilities meet the criteria established by paragraph B.1. of this part, the following methodology will be used:

(a) *Provision of Services to a Designated Area or Population Group.*

A facility will be considered to be providing services to an area or population group if either:

(i) A majority of the facility's dental care services are being provided to residents of designated dental manpower shortage areas or to population groups designated as having a shortage of dental manpower; or

(ii) The population within a designated dental shortage area or population group has reasonable access to dental services provided at the facility. Reasonable access will be assumed if the population lies within 40 minutes travel time of the facility and nonphysical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

Migrant health centers (as defined in section 319(a)(1) of the Act) which are located in areas with designated migrant population groups and Indian Health Service facilities are assumed to be meeting this requirement.

(b) *Insufficient Capacity To Meet Dental Care Needs.*

A facility will be considered to have insufficient capacity to meet the dental care needs of a designated area or population group if either of the following conditions exists at the facility.

(i) There are more than 5,000 outpatient visits per year per FTE dentist on the staff of the facility. (Here the number of FTE dentists is computed as in Part I, Section B, paragraph 3 above.)

(ii) Waiting time for appointments is more than 6 weeks for routine dental services.

3. *Determination of Degree of Shortage.*

Each designated dental facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

Appendix C—Criteria for Designation of Areas having Shortages of Psychiatric Manpower

Part I—Geographic Areas

A. *Criteria.*

A geographic area will be designated as having a shortage of psychiatric manpower if the following three criteria are met:

1. The area is a rational area for the delivery of psychiatric services.

2. One of the following conditions prevails within the area:

(a) The area has a population to full-time-equivalent psychiatrist ratio of at least 30,000:1; or

(b) The area has a population to full-time-equivalent psychiatrist ratio of less than 30,000:1 but greater than 20,000:1 and has unusually high needs for psychiatric services.

3. Psychiatric manpower in contiguous areas are overutilized, excessively distant or inaccessible to residents of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this Part, the following methodology will be used:

1. *Rational Areas for the Delivery of Psychiatric Services.*

(a) The following areas will be considered rational areas for the delivery of psychiatric services:

(i) An established mental health catchment area, as designated in the State Mental Health Plan under the general crite-

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ria set forth in section 238 of the Community Mental Health Centers Act.

(ii) A portion of an established mental health catchment area whose population, because of topography, market and/or transportation patterns or other factors, has limited access to psychiatric resources in the rest of the catchment area, as measured generally by a travel time of greater than 40 minutes to these resources.

(iii) A county or metropolitan area which contains more than one mental health catchment area, where data are unavailable by individual catchment area.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

2. *Population Count.*

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions.

3. *Counting of Psychiatrists.*

(a) All non-Federal psychiatrists providing patient care (direct or other, including consultation and supervision) in ambulatory or other short-term care settings to residents of the area more than one-half day per week will be counted. Those psychiatrists engaged solely in administration, research, and teaching will be excluded. Adjustments for the following factors will be made in computing the number of full-time-equivalent (FTE) psychiatrists:

(i) Psychiatric residents will be counted as 0.5 FTE psychiatrists.

(ii) Graduates of foreign medical schools who are not citizens or lawful permanent residents of the United States will be excluded from psychiatrist counts.

(iii) Those graduates of foreign medical schools who are citizens or lawful permanent residents of the United States, but do not have unrestricted licenses to practice medicine, will be counted as 0.5 FTE psychiatrists.

(b) Psychiatrists who are semi-retired, who operate a reduced practice due to infirmity or other limiting conditions, or who provide patient care to the population of an area only on a part-time basis will be discounted through the use of "full-time equivalency" figures. A 40-hour work week will be used as the standard for determining full-time equivalents in these cases. For practitioners working less than a 40-hour week, every 4 hours (or ½ day) spent providing patient care services in ambulatory or inpatient settings will be counted as 0.1 FTE, and each psychiatrist providing patient care 40 or more hours a week will be counted as 1.0 FTE. For cases where data are available only for hours providing care in office settings, equivalencies will be provided in guidelines.

(c) In some cases, psychiatrists located within an area may not be accessible to the general population of the area under consideration. Allowances for psychiatrists working in restricted facilities will be made on a case-by-case basis. Examples of restricted practices include staff positions in correctional institutions, youth detention facilities, residential treatment centers for emotionally disturbed or mentally retarded children, and inpatient units of State or county mental hospitals.

(d) In cases where there are mental health facilities or institutions providing both inpatient and outpatient services, those psychiatrists assigned to outpatient or other short-term care units will be counted. If the psychiatric staff is not specifically allocated to one service or the other, the number of psychiatrists in short-term care will be estimated on the basis of the relative workload in each type of setting.

(e) Psychiatrists who are suspended for a period of eighteen months or more under provisions of the Medicare-Medicaid Anti-Fraud and Abuse Act will not be counted.

4. *Determination of Unusually High Need for Psychiatric Services.*

An area will be considered to have unusually high needs for psychiatric services if two or more of the following criteria are met:

(a) 20 percent of the population (or of all households) have incomes below the poverty level, or the area has been designated as a poverty area in accordance with section 242 of the Community Mental Health Centers Act.

(b) A young dependency ratio (ratio of children under 18 to population 18-64) in excess of 60 percent.

(c) An aged dependency ratio (ratio of persons aged 65 and over to population 18-64) in excess of 25 percent.

(d) A high prevalence of alcoholism in the population, as indicated by a value of 0.211 for the catchment area's index of relative alcoholism prevalence (as developed by the National Institute of Alcohol Abuse and Alcoholism for the purposes of allocating funds over 42 U.S.C. 4571).

5. *Contiguous Area Considerations.*

Psychiatric manpower in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of

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the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Psychiatrists in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation (measured in accordance with paragraph B.1(b) of this part).

(b) Contiguous area population-to-FTE psychiatrist ratios are in excess of 20,000:1, indicating that psychiatrists in contiguous areas cannot be expected to help alleviate the shortage situation in the area for which designation is being considered.

(c) Psychiatric manpower in contiguous areas are inaccessible to the population of the requested area because of geographic, cultural, language or other barriers or because of residency restrictions of programs or facilities providing such manpower.

C. *Determination of Degree of Shortage*

Designated areas will be assigned to degree-of-shortage groups, based on the ratio (R) of population to number of FTE psychiatrists and the presence or absence of unusually high needs for psychiatric services, according to the following table:

	High needs not indicated	High needs indicated
Group 1	No psychiatrists	No psychiatrists.
Group 2	$R>50,000$	$R>40,000$.
Group 3	$50,000>R>40,000$	$40,000>R>30,000$.
Group 4	$40,000>R>30,000$	$30,000>R>20,000$.

Part II—Population Groups

Population groups within particular catchment areas will be designated as having a psychiatric manpower shortage if the following conditions prevail:

(a) Access barriers prevent the population group from using those psychiatric manpower which are present in the area, and

(b) The ratio of the number of persons in the population group to the number of FTE psychiatrists serving the population group, and practicing within 40 minutes travel time of the center of the area where the population group resides, is at least 30,000:1 (20,000:1 where unusally high needs for psychiatric services are indicated).

B. *Determination of Degree of Shortage.*

Designated population groups will be assigned to degree-of-shortage groups as in Section C of Part I of this Appendix, based on the ratio of the group's population to the number of psychiatrists serving it, together with the presence or absence of unusually high needs for psychiatric services among the population group.

Part III—Facilities

A. *Federal and State Correctional Institutions*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions for adults or youth, and youth detention facilities, will be designated as having a shortage of psychiatric manpower if both of the following criteria are met:

(a) The institution has more than 250 inmates, and

(b) The ratio of the number of internees per year to the number of FTE psychiatrists serving the institution is at least 2,000:1. (Here the number of internees is the number of inmates or residents present at the beginning of the year, plus the number of new inmates or residents entering the institution during the year, including those who left before the end of the year; the number of FTE psychiatrists is computed as in Part I, Section B, paragraph 3 above.)

2. *Determination of Degree of Shortage.*

Correctional facilities and youth detention facilities will be assigned to degree-of-shortage groups, based on the number of inmates and/or the ratio (R) of internees to FTE psychiatrists, as follows:

Group 1—Facilities with 500 or more inmates or residents and no psychiatrist.

Group 2—Other facilities with no psychiatrists and facilities with 500 or more inmates or residents and $R>3,000$.

Group 3—All other facilities.

B. *State and County Mental Hospitals.*

1. *Criteria.*

A State or county hospital will be designated as having a shortage of psychiatric manpower if both of the following criteria are met:

(a) The mental hospital has an average daily inpatient census of at least 100; and

(b) The number of workload units per FTE psychiatrists available at the hospital exceeds 300, where workload units are calculated using the following formula:

Total workload units = average daily inpatient census + 2 × (number of inpatient admissions per year) + 0.5 × (number of admissions to day care and outpatient services per year).

2. *Determination of Degree of Shortage.*

State or county mental hospitals will be assigned to degree-of-shortage groups, based on the ratio (R) of workload units to number of FTE psychiatrists, as follows:

Group 1—No psychiatrists, or $R>1,800$.

Group 2—$1,800>R>1,200$.

Group 3—$1,200>R>600$.

Group 4—$600>R>300$.

C. *Community Mental Health Centers and Other Public or Nonprofit Private Facilities.*

1. *Criteria.*

A community mental health center (CMHC), authorized by Pub. L. 94-63, or other public or nonprofit private facility

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providing psychiatric services to an area or population group, may be designated as having a shortage of psychiatric manpower if the facility is providing (or is responsible for providing) psychiatric services to an area or population group designated as having a psychiatric manpower shortage, and the facility has insufficient capacity to meet the psychiatric needs of the area or population group.

2. *Methodology.*

In determining whether CMHCs or other public or nonprofit private facilities meet the criteria established in paragraph C.1 of this Part, the following methodology will be used.

(a) *Provision of Services to a Designated Area or Population Group.*

The facility will be considered to be providing services to a designated area or population group if either:

(i) A majority of the facility's psychiatric services are being provided to residents of designated psychiatric manpower shortage areas or to population groups designated as having a shortage of psychiatric manpower; or

(ii) The population within a designated psychiatric shortage area or population group has reasonable access to psychiatric services provided at the facility. Such reasonable access will be assumed if the population lies within 40 minutes travel time of the facility and nonphysical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

(b) *Responsibility for Provision of Services.*

This condition will be considered to be met if the facility, by Federal or State statute, administrative action, or contractual agreement, has been given responsibility for providing and/or coordinating psychiatric services for the area or population group, consistent with applicable State plans.

(c) *Insufficient Capacity to Meet Psychiatric Needs.*

A facility will be considered to have insufficient capacity to meet the psychiatric needs of the area or population it serves if:

(i) There are more than 3,000 patient visits per year per FTE psychiatrist on the staff are under care at the facility, or

(ii) No psychiatrists are on the staff and this facility is the only facility providing (or responsible for providing) services to the designated area or population.

3. *Determination of Degree-of-Shortage.*

Each designated facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

APPENDIX D—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VISION CARE MANPOWER

Part I—Geographic Areas

A. *Criteria.*

A geographic area will be designated as having a shortage of vision care manpower if the following three criteria are met:

1. The area is a rational area for the delivery of vision care services.

2. The estimated number of optometric visits supplied by vision care manpower in the area is less than the estimated requirements of the area's population for these visits, and the computed shortage is at least 1,500 optometric visits.

3. Vision care manpower in contiguous areas are excessively distant, overutilized, or inaccessible to the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Vision Care Services.*

(a) The following areas will be considered rational areas for the delivery of vision care services:

(i) A county, or a group of contiguous counties whose population centers are within 40 minutes travel time of each other;

(ii) A portion of a county (or an area made up of portions of more than one county) whose population, because of topography, market or transportation patterns, or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

2. *Determination of Estimated Requirement for Optometric Visits.*

The number of optometric visits required by an area's population will be estimated by multiplying each of the following visit rates by the size of the population within that particular age group and then adding the figures obtained together.

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Age	Annual number of optometric visits required per person, by age					
	Under 20	20-29	30-39	40-49	50-59	60 and over
Number of visits	0.11	0.20	0.24	0.35	0.41	0.48

For geographic areas where the age distribution of the population is not known, it will be assumed that the percentage distribution, by age groups, for the area is the same as the distribution for the county of which it is a part.

(3) *Determination of Estimated Supply of Optometric Visits.*

The estimated supply of optometric services will be determined by use of the following formula:

Optometric visits supplied = 3,000 × (number of optometrists under 65)
Optometric visits supplied + 2,000 × (number of optometrists 65 and over)
Optometric visits supplied + 1,500 × (number of ophthamologists)

(4) *Determination of Size of Shortage.*

Size of shortage (in number of optometric visits) will be computed as follows:

Optometric visit shortage = visits required − visits supplied

(5) *Contiguous Area Considerations.*

Vision care manpower in area contiguous to an area being considered for designation will be considered exececessively distant, overutilized or inaccessible to the population of the area if one of the following conditions prevails in each contiguous area:

(a) Vision care manpower in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation (measured in accordance with paragraph B.1(b) of this Part).

(b) The estimated requirement for vision care services in the contiguous area exceeds the estimated supply of such services there, based on the requirements and supply calculations previously described.

(c) Vision care manpower in the contiguous area are inaccessible to the population of the area because of specified access barriers (such as economic or cultural barriers).

C. *Determination of Degree-of-Shortage.*

Designated areas (and population groups) will be assigned to degree-of-shortage groups, based on the ratio of optometric visits supplied to optometric visits required for the area (or group), as follows:

Group 1—Areas (or groups) with no optometric visits being supplied (i.e., with no optometrists or ophthalmologists).

Group 2—Areas (or groups) where the ratio of optometric visits supplied to optometric visits required is less than 0.5.

Group 3—Areas (or groups) where the ratio of optometric visits supplied to optometric visits required is between 0.5 and 1.0.

Part II—Population Groups

A. *Criteria.*

Population groups within particular geographic areas will be designated if both the following criteria are met:

(1) Members of the population group do not have access to vision care resources within the area (or in contiguous areas) because of non-physical access barriers (such as economic or cultural barriers).

(2) The estimated number of optometric visits supplied to the population group (as determined under paragraph B.3 of Part I of this Appendix) is less than the estimated number of visits required by that group (as determined under paragraph B.2 of Part I of this Appendix), and the computed shortage is at least 1,500 optometric visits.

B. *Determination of Degree of Shortage.*

The degree of shortage of a given population group will be determined in the same way as described for areas in paragraph C of Part I of this Appendix.

APPENDIX E—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PODIATRIC MANPOWER

Part I—Geographic Areas

A. *Criteria.*

A geographic area will be designated as having a shortage of podiatric manpower if the following three criteria are met:

1. The area is a rational area for the delivery of podiatric services.
2. The area's ratio of population to foot care practitioners is at least 28,000:1, and the computed podiatrist shortage to meet this ratio is at least 0.5.
3. Podiatric manpower in contiguous areas are overutilized, excessively distant, or inaccessible to the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this Part, the following methodology will be used:

1. *Rational Areas for the Delivery of Podiatric Services.*

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(a) The following areas will be considered rational areas for the delivery of podiatric services:

(i) A county or a group of contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market and/or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes from its population center to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the area corresponding to 40 minutes travel time.

2. *Population Count.*

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions, adjusted by the following formula to take into account the differing utilization rates of podiatric services by different age groups within the population:

Adjusted population = total population × (1 + 2.2 × (percent of population 65 and over) − 0.44 × (percent of population under 17)).

3. *Counting of Foot Care Practitioners.*

(a) All podiatrists providing patient care will be counted. However, in order to take into account productivity differences in podiatric practices associated with the age of the podiatrists, the following formula will be utilized:

Number of FTE podiatrists = 1.0 × (podiatrists under age 55)
+ .8 × (podiatrists age 55 and over)

(b) In order to take into account the fact that orthopedic surgeons and general and family practitioners devote a percentage of their time to foot care, the total available foot care practitioners will be computed as follows:

Number of foot care practitioners = number of FTE podiatrists
+ .15 × (number of orthopedic surgeons)
+ .02 × (number of general and family practioners).

4. *Determination of Size of Shortage.*

Size of shortage (in number of FTE podiatrists) will be computed as follows:

Podiatrist shortage = adjusted population/28,000 − number of FTE foot care practitioners.

5. *Contiguous Area Considerations.*

Podiatric manpower in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Podiatric manpower in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation.

(b) The population-to-foot care practitioner ratio in the contiguous areas is in excess of 20,000 : 1, indicating that contiguous area podiatric manpower cannot be expected to help alleviate the shortage situation in the area for which designation is requested.

(c) Podiatric manpower in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers (such as economic or cultural barriers).

C. *Determination of Degree of Shortage.*

Designated areas will be assigned to groups, based on the ratio (R) of adjusted population to number of foot care practitioners, as follows:

Group 1 Areas with no foot care practitioners, and areas with R > 50,000 and no podiatrists.
Group 2 Other areas with R > 50,000.
Group 3 Areas with 50,000 > R > 28,000.

APPENDIX F—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PHARMACY MANPOWER

Part 1—Geographic Areas

A. *Criteria.*

A geographic area will be designated as having a shortage of pharmacy manpower if the following three criteria are met:

1. The area is a rational area for the delivery of pharmacy services.

2. The number of pharmacists serving the area is less than the estimated requirement for pharmacists in the area, and the computed pharmacist shortage is at least 0.5.

3. Pharmacists in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this Part, the following methodology will be used:

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1. *Rational Areas for the Delivery of Pharmacy Services.*

(a) The following areas will be considered rational areas for the delivery of pharmacy services:

(i) A county, or a group of contiguous counties whose population centers are within 30 minutes travel time of each other; and

(ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 30 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 30 minutes travel time:

(i) Under normal conditions with primary roads available: 20 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 15 miles.

(iii) In flat terrain or in areas connected by interstate highways: 25 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the area corresponding to 30 minutes travel time.

2. *Counting of Pharmacists.*

All active pharmacists within the area will be counted, except those engaged in teaching, administration, or pharmaceutical research.

3. *Determination of Estimated Requirement for Pharmacists.*

(a) *Basic estimate.* The basic estimated requirement for pharmacists will be calculated as follows:

Basic pharmacist requirement = .15 × (resident civilian population/1,000) + .035 × (total number of physicians engaged in patient care in the area).

(b) *Adjusted estimate.* For areas with less than 20,000 persons, the following adjustment is made to the basic estimate to compensate for the lower expected productivity of small practices.

Estimated pharmacist requirement = (2 − population/20,000) × basic pharmacist requirement.

4. *Size of Shortage Computation.*

The size of the shortage will be computed as follows:

Pharmacist shortage = estimated pharmacist requirement − number of pharmacists available.

5. *Contiguous Area Considerations.*

Pharmacists in areas contiguous to an area being considered for designation will be considered excessively distant or overutilized if either:

(a) Pharmacy manpower in contiguous areas are more than 30 minutes travel time from the center of the area under consideration, or

(b) The number of pharmacists in each contiguous area is less than or equal to the estimated requirement for pharmacists for that contiguous area (as computed above).

C. *Determination of Degree-of-Shortage.*

Designated areas will be assigned to degree-of-shortage groups, based on the proportion of the estimated requirement for pharmacists which is currently available in the area, as follows:

Group 1—Areas with no pharmacists.

Group 2—Areas where the ratio of available pharmacists to pharmacists required is less than 0.5.

Group 3—Areas where the ratio of available pharmacists to pharmacists required is between 0.5 and 1.0.

APPENDIX G—CRITERIA FOR THE DESIGNATION OF AREAS HAVING SHORTAGES OF VETERINARY MANPOWER

Part I—Geographic Areas

A. *Criteria for Food Animal Veterinary Shortage.*

A geographic area will be designated as having a shortage of food animal veterinary manpower if the following three criteria are met:

1. The area is a rational area for the delivery of veterinary services.

2. The ratio of veterinary livestock units to food animal veterinarians in the area is at least 10,000 : 1, and the computed food animal veterinarian shortage to meet this ratio is at least 0.5.

3. Food animal veterinarians in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

B. *Criteria for Companion Animal Veterinary Shortage.*

A geographic area will be designated as having a shortage of companion animal veterinary manpower if the following three criteria are met:

1. The area is a rational area for the delivery of veterinary services.

2. The ratio of resident civilian population to number of companion animal veterinarians in the area is at least 30,000 : 1 and the computed companion animal veterinary shortage to meet this ratio is at least 0.5.

3. Companion animal veterinarians in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

C. *Methodology.*

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In determining whether an area meets the criteria established by paragraphs A and B of this Part, the following methodology will be used:

1. *Rational Areas for the Delivery of Veterinary Services.*

(a) The following areas will be considered rational areas for the delivery of veterinary services:

(i) A county, or a group of contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county (or an area made up of portions of more than one county) which, because of topography, market and/or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

2. *Determination of Number of Veterinary Livestock Units (VLU) Requiring Care.*

Since various types of food animals require varying amounts of veterinary care, each type of animal has been assigned a weight indicating the amount of veterinary care it requires relative to that required by a milk cow. Those weights are used to compute the number of "Veterinary Livestock Units" (VLU) for which veterinary care is required.

The VLU is computed as follows:

Veterinary Livestock Units (VLU) = (number of milk cows)
+ .2 × (number of other cattle and calves)
+ .05 × (number of hogs and pigs)
+ .05 × (number of sheep)
+ .002 × (number of poultry).

3. *Counting of Food Animal Veterinarians.*

The number of food animal veterinarians is determined by weighting the number of veterinarians within each of several practice categories according to the average fraction of practice time in that category which is devoted to food animal veterinary care, as follows:

Number of Food Animal Veterinarians = (number of veterinarians in large animal practice, exclusively)
+ (number of veterinarians in bovine practice, exclusively)
+ (number of veterinarians in poultry practice, exclusively)
+ .75 × (mixed practice veterinarians with greater than 50% of practice in large animal care)
+ .5 × (mixed practice veterinarians with approximately 50% of practice in large animal care)
+ .25 × (mixed practice veterinarians with less than 50% of practice in large animal care).

4. *Counting of Companion Animal Veterinarians* (that is, those who provide services for dogs, cats, horses, and any other animals maintained as companions to the owner rather than as food animals).

The number of full-time equivalent companion animal veterinarians is determined by weighting the number of veterinarians within each of several practice categories by the average portion of their practice which is devoted to companion animal care by the practitioners within that category, as follows:

Number of Companion Animal Veterinarians = (number of veterinarians in large animal practice, exclusively)
+ (number of veterinarians in equine practice, exclusively)
+ .75 × (mixed practice veterinarians with greater than 50% of practice in small animal care)
+ .5 × (mixed practice veterinarians with approximately 50% of practice in small animal care)
+ .25 × (mixed practice veterinarians with less than 50% of practice in small animal care).

5. *Size of Shortage Computation.*

The size of shortage will be computed as follows:

(a) Food animal veterinarian shortage = (VLU/10,000) − (number of food animal veterinarians).

(b) Companion animal veterinarian shortage = (resident civilian pop./30,000) − (number of companion animal veterinarians).

6. *Contiguous Area Considerations.*

Veterinary manpower in areas contiguous to an area being considered for designation will be considered excessively distant from the population of the area or overutilized if one of the following conditions prevails in each contiguous area:

(a) Veterinary manpower in the contiguous area are more than 60 minutes travel time from the center of the area being considered for designation (measured in accordance with paragraph C.1.(b) of this Part).

(b) In the case of food animal veterinary manpower, the VLU-to-food animal veterinarian ratio in the contiguous area is in excess of 5,000 : 1.

(c) In the case of companion animal veterinary manpower, the population-to-com-

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panion animal veterinarian ratio in the contiguous area is in excess of 15,000 : 1.

C. *Determination of Degree-of-Shortage.*

Designated areas will be assigned to degree-of-shortage groups as follows:

Group 1—Areas with a food animal veterinarian shortage and no veterinarians.

Group 2—Areas (not included above) with a food animal veterinarian shortage and no food animal veterinarians.

Group 3—All other food animal veterinarian shortage areas.

Group 4—All companion animal shortage areas (not included above) having no veterinarians.

Group 5—All other companion animal shortage areas.

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SUBCHAPTER B—PERSONNEL

PART 21—COMMISSIONED OFFICERS

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Subpart A—Definitions

§ 21.1 Meaning of terms.

As used in this part, the term:

(a) "Act" means the Public Health Service Act, 58 Stat. 682, as now or hereafter amended.

(b) "Department" means the Department of Health and Human Services.

(c) "Secretary" means the Secretary of Health and Human Services.

(d) "Service" means the Public Health Service.

(e) "Surgeon General" means the Surgeon General of the Public Health Service.

(f) "Commissioned officer" or "officer", unless otherwise indicated, means either an officer of the Regular Corps or an officer of the Reserve Corps.

(Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216)

[21 FR 9806, Dec. 12, 1956]

Subpart B—Appointment

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216; sec. 208, 58 Stat. 685, as amended; 42 U.S.C. 209.

SOURCE: 21 FR 9806, Dec. 12, 1956. Redesignated at 44 FR 46846, Aug. 6, 1979, unless otherwise noted.

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§ 21.21 Meaning of terms.

The terms "approved school", "approved college", "approved postgraduate school", or "approved training course" means, except as otherwise provided by law:

(a) A school, college, postgraduate school, or training course which has been accredited or approved by a professional body or bodies recognized by the Surgeon General for such purpose, or which, in the absence of such a

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body, meets generally accepted professional standards as determined by the Surgeon General, or

(b) In the case of a candidate who is applying for appointment as a medical officer, any non-approved medical school provided that the candidate has passed examinations given by a professional body or bodies recognized by the Surgeon General for such purpose.

[24 FR 1790, Mar. 12, 1959. Redesignated at 44 FR 46846, Aug. 6, 1979]

§ 21.22 Submission of application and evidence of qualifications.

(a) *Application form.* Every candidate for examination for appointment as an officer shall submit a written application on such form as may be prescribed by the Surgeon General.

(b) *Documentary evidence.* The application shall be accompanied by such documentary evidence as may be required by the Surgeon General.

§ 21.23 False statements as disqualification.

Willfully false statements shall be cause for rejection of the application or, as provided in Subpart N of this part, for dismissal.

§ 21.24 Physical examinations.

Every candidate for appointment as an officer shall undergo such physical examination as the Surgeon General may direct, and no candidate who is not found to be physically qualified shall be appointed as an officer.

§ 21.25 Eligibility; junior assistant grade.

(a) *Requirements; all candidates.* Except as provided in § 21.54, and as otherwise provided in this section, every candidate for examination for appointment in the grade of junior assistant:

(1) Shall be a citizen of the United States;

(2) Shall be at least 18 years of age; and

(3) Shall have been granted an academic or professional degree from an approved school, college, or postgraduate school, and, unless the required professional training has been otherwise obtained from an approved school, college, or postgraduate school, shall have majored in the profession in which the examination is being held.

(b) [Reserved]

(c) *Special requirement; therapists.* Every candidate for examination for appointment as a therapist shall have received a certificate from an approved school of physical therapy or an approved school of occupational therapy.

[21 FR 9806, Dec. 12, 1956, as amended at 30 FR 9437, July 29, 1965. Redesignated at 44 FR 46846, Aug. 6, 1979]

§ 21.26 Eligibility; assistant grade.

(a) *Requirements; all candidates.* Except as otherwise provided in this section every candidate for examination for appointment in the grade of assistant:

(1) Shall meet the requirements for eligibility for examination for appointment in the grade of junior assistant;

(2) Shall be at least 21 years of age; and

(3) Shall have had at least 7 years of educational and professional training or experience subsequent to high school, except that a candidate who applies for examination for appointment in the Reserve Corps to serve as a medical or dental intern may be examined for such appointment upon the completion of 6 years of such education, training, or experience.

(b) *Additional requirements; dietitians.* Every candidate for examination for appointment as a dietitian shall have successfully completed an approved training course for dietetic interns.

§ 21.27 Eligibility; senior assistant grade.

Every candidate for examination for appointment in the grade of senior assistant shall meet the requirements for eligibility for examination for appointment in the grade of assistant and shall have completed at least 10 years of educational and professional training or experience subsequent to high school.

§ 21.28 Age requirements, Regular Corps, senior assistant grade and below.

No candidate for appointment to the Regular Corps, except in the nurse category, shall be appointed (a) after age 31 to the permanent junior assistant grade, (b) after age 34 to the permanent assistant grade, or (c) after age 37 to the permanent senior assistant grade: *Provided*, That the Surgeon General may waive these age limitations, subject to other provisions of law, in the case of any officer of the Reserve Corps who is recommended for appointment to the Regular Corps by the Chief of the Bureau to which he is assigned and who has been on continuous active duty for at least two years immediately preceding the date of such recommendation. The age limitations for candidates who have had prior active service in the Commissioned Corps of the Public Health Service shall be increased by the period of such service.

[27 FR 3886, Apr. 24, 1962. Redesignated at 44 FR 46846, Aug. 6, 1979]

§ 21.29 Eligibility; grades above senior assistant grade.

Every candidate for examination for appointment in grades above that of senior assistant shall meet the requirements for eligibility for examination for appointment in the grade of senior assistant. Candidates for examination for appointment in the full, senior, or director grade shall have completed at least 7, 14, or 15 additional years, respectively, of postgraduate professional training for experience. When officers of the Service are unavailable for the performance of duties requiring highly specialized training and experience in special fields related to public health, the Surgeon General may specify that a candidate for appointment to the Regular Corps with such highly specialized training and experience shall be examined for appointment in the full or senior grade upon completion of at least 5 or 12 additional years, respectively, of postgraduate professional training or experience, except that the total number of such appointments during a fiscal year shall not exceed three.

[21 FR 9806, Dec. 12, 1956. Redesignated at 25 FR 5134, June 10, 1960, and at 44 FR 46846, Aug. 6, 1979]

§ 21.30 Determination of creditable years of educational and professional training and experience.

The level of academic attainment, the number of calendar years and the quality of educational and professional training and experience shall be considered in determining the number of years of such training and experience with which each candidate for appointment may be credited.

[25 FR 5184, June 10, 1960. Redesignated at 44 FR 46846, Aug. 6, 1979]

§ 21.31 Eligibility; all grades; academic and professional education and professional training and experience.

The Surgeon General is authorized, subject to the other provisions of this subpart to adopt additional standards by which the education, training, and experience required under this subpart, and evidence thereof, shall be of such specific kind and quality, pertinent to the particular profession concerned, as in his judgment are necessary to limit the examination to qualified candidates.

[25 FR 5184, June 10, 1960. Redesignated at 44 FR 46846, Aug. 6, 1979]

§ 21.32 Boards; appointment of; powers and duties.

The Surgeon General shall from time to time appoint boards and subboards of officers to consider the qualifications of candidates for appointment as officers, and shall refer to such boards the applications of those candidates who are eligible for examination for appointment. Such boards and subboards shall consist of three or more officers, the majority of whom, so far as practicable, shall be of the same profession as the candidate. The Surgeon General shall prescribe the duties of boards and subboards in relation to the examination process not otherwise prescribed in this subpart.

[21 FR 9806, Dec. 12, 1956. Redesignated at 25 FR 5184, June 10, 1960, and at 44 FR 46846, Aug. 6, 1979]

§ 21.33 General service.

Officers shall be appointed only to general service and shall be subject to change of station.

[21 FR 9806, Dec. 12, 1956. Redesignated at 25 FR 5184, June 10, 1960, and at 44 FR 46846, Aug. 6, 1979]

§ 21.34 Certification by candidate; requirement of new physical examination.

If a candidate for appointment in the Regular Corps or an officer of the Reserve Corps on inactive service has passed a physical examination within a period of one year from the date on which it is contemplated that he will be appointed or called to active duty, he shall, prior to being appointed or called to active duty, certify that to the best of his knowledge and belief he is free from all disease or injury not noted in his record at the time of his examination and that he is willing to serve in any climate. If a candidate for appointment in the Regular Corps, or an officer of the Reserve Corps on inactive service, has not passed a physical examination within a period of one year from the date on which it is contemplated that he will be appointed or called to active duty, he may, prior to being appointed or called to active duty, be required to undergo such physical examination as the Surgeon General may direct to determine his physical qualification for appointment or call to active duty in accordance with standards prescribed for original appointment, or he may be appointed or called to active duty after executing the certificate described in this section, but shall be physically examined to determine his physical qualification for continued active service in accordance with standards prescribed for original appointment within a period of 15 days after reporting for duty at his first station.

[21 FR 9806, Dec. 12, 1956, as amended at 24 FR 1790, Mar. 12, 1959. Redesignated at 25 FR 5184, June 10, 1960, and at 44 FR 46846, Aug. 6, 1979]

PROVISIONS APPLICABLE ONLY TO REGULAR CORPS

§ 21.41 Professional examinations, holding of; subjects to be included.

From time to time the Surgeon General may order examinations to be held in such professions or specialties within professions and for such grades as he deems necessary for the purpose of providing merit rolls of eligible candidates for appointment in the Regular Corps and shall, if a professional examination is to be required, prescribe the subjects relating to each profession or specialty within such profession in which candidates will be examined.

[21 FR 9806, Dec. 12, 1956, as amended at 24 FR 1790, Mar. 12, 1959. Redesignated at 44 FR 46846, Aug. 6, 1979]

§ 21.42 Examinations; junior assistant, assistant, or senior assistant grade.

The examination for appointment to the junior assistant, assistant, or senior assistant grade in the Regular Corps shall consist of (a) a written professional examination relating to the fundamentals of the candidate's profession or specialty within his profession and their relationship to the activities of the Service, and (b) an examination as to the candidate's general fitness, which shall include an oral interview, and a review and evaluation of the candidate's academic and professional education and professional training and experience, and may include other written tests to determine the candidate's fitness for appointment as an officer. If an applicant for appointment to any of these grades is an officer of the Reserve Corps who has been on active duty for not less than one year immediately preceding his application, the Surgeon General may direct that the officer be examined as provided in § 21.43.

[21 FR 9806, Dec. 12, 1956, as amended at 24 FR 1790, Mar. 12, 1959, 25 FR 11099, Nov. 23, 1960. Redesignated at 44 FR 46846, Aug. 6, 1979]

§ 21.43 Examination; full grade and above.

The examination for appointment to the full, senior, or director grade in the Regular Corps shall consist of a review and evaluation of the candidate's academic and professional education and professional training and experience. The Surgeon General may, however, direct that the examination of a candidate for appointment to any such grade shall also include an oral interview, a written or oral professional examination, or both.

§ 21.44 Clinical or other practical demonstration.

In the discretion of the Surgeon General a candidate for appointment to any grade up to and including the senior assistant grade in the Regular Corps may be required to perform successfully a clinical or other practical demonstration which, if required, shall constitute a part of the professional examination.

§ 21.45 Rating values.

The examination of every candidate for appointment to any grade in the Regular Corps shall be rated by a board appointed pursuant to § 21.30 in accordance with such relative values for each part of the examination as are prescribed by the Surgeon General. No candidate who receives a final rating below 80 shall be appointed in the Regular Corps.

§ 21.46 Merit roll.

Each board appointed pursuant to § 21.30 to consider the qualifications of candidates for appointment as officers shall assign a numerical rating to each candidate for appointment in the Regular Corps who passes the examination, and shall submit a report to the Surgeon General of the ratings and the relative standing of all such candidates for each grade in each profession or specialty within a profession. The Surgeon General shall submit each such report with his recommendations to the Secretary, and, if approved by the Secretary, the report shall constitute a merit roll from which the Secretary shall, in accordance with relative standing, recommend available persons to the President for nomination as commissioned officers of the Regular Corps. A board may consider any newly discovered evidence relating to the physical, professional, or personal qualifications of any candidate examined for appointment. Upon recommendation of such board after review of such evidence, the Surgeon General, with the approval of the Secretary, may correct the rating of a candidate or may qualify or disqualify a candidate. The placing of a candidate's name on a merit roll shall give no assurance of an appointment. A merit roll shall expire when a new merit roll in the same profession or specialty within a profession and grade has been established, but no merit roll shall continue in effect longer than two years after its approval by the Secretary. Every candidate who has not been nominated by the President for appointment prior to the expiration of a merit roll on which his name appears, shall, unless he requests the opportunity to be reexamined, be rated with the next group of candidates of the same profession or specialty within a profession for appointment in the same grade and shall be given the same rating he had on the expired merit roll. If two candidates who were examined at the same time receive the same numerical rating the elder candidate shall assume relative standing on the merit roll over the younger candidate. If a candidate whose name is being transferred from an expired to a new merit roll has the same numerical rating as a candidate whose name is being placed on the new merit roll for the first time, the former shall assume relative standing on the merit roll over the latter. The name of a candidate may be removed from a merit roll in the event that he refuses an appointment when offered. No candidate's eligibility for appointment shall exceed two years unless he again becomes eligible as the result of another examination.

[21 FR 9806, Dec. 12, 1956, as amended at 24 FR 1790, Mar. 12, 1959. Redesignated at 44 FR 46846, Aug. 6, 1979]

§ 21.47 Examination; anticipation of meeting qualifications.

A potential candidate for appointment in any grade in the Regular Corps may be examined within a period of nine months prior to the date upon which it is anticipated that he will qualify for appointment under this subpart. Upon successful completion of the examination, his name will be entered on a merit roll. In the event that his name, in order of relative standing among all candidates, precedes that of fully qualified candidates, his name, for purpose of appointment, shall be passed over in favor of fully qualified candidates until such time as he becomes fully qualified, but in no event shall he otherwise lose his relative standing on the merit roll, except as provided in § 21.46. If the candidate fails to qualify for appointment at the time that it was anticipated that he would qualify, his name shall be removed from the merit roll.

PROVISIONS APPLICABLE ONLY TO RESERVE CORPS

§ 21.51 Appointment of officers having specialized training or experience in administration and management.

The Surgeon General may recommend for original appointment in the Reserve Corps candidates who have specialized training or experience in administration and management relating to the functions of the Service. All such candidates shall be subject to the same eligibility requirements for original appointment as are applicable to other candidates, except that such a candidate may substitute experience in administration or management for the requirement of professional training or experience.

§ 21.52 Waiver of entrance qualifications for original appointment in time of war or national emergency.

If, in time of war or national emergency proclaimed by the President, the Secretary determines that there is need for commissioned personnel to meet the needs of the Service, other than persons eligible for examination for original appointment under the eligibility requirements prescribed in this subpart, he may prescribe standards of eligibility for examination for the original appointment of officers in the Reserve Corps without regard to such eligibility requirements. Such standards shall, however, authorize the examination only of candidates with specialized experience in administration or management or candidates with training or experience in fields relating to public health. The permanent grade of an officer who becomes eligible for examination for appointment pursuant to such standards and who becomes eligible for appointment after passage of an examination shall be limited to the junior assistant or the assistant grade, except that, if upon examination a candidate is found to be exceptionally qualified for the performance of highly specialized duties with the Service pursuant to § 21.55, he may be recommended for appointment to any grade up to and including the director grade.

[21 FR 9806, Dec. 12, 1956, as amended at 24 FR 1790, Mar. 12, 1959. Redesignated at 44 FR 46846, Aug. 6, 1979]

§ 21.53 Examination.

The examination of candidates for original appointment as officers to any grade in the Reserve Corps shall consist of a review and evaluation of their academic and other education and their training and experience. In the discretion of the Surgeon General the examination of any such candidate may include an oral interview, a written examination, or both.

§ 21.54 Students.

A potential candidate for appointment in the Regular Corps who is pursuing a course of instruction which, upon completion, would qualify him under §§ 21.25 or 21.26 for examination for appointment in the junior assistant or assistant grade may be examined for and appointed in the Reserve Corps in the junior assistant grade but shall not be called to extended active duty until the successful completion of such course of instruction, except that: (a) He may be called to active duty for purposes of training for periods not to exceed 120 days during any fiscal year, and (b) those students who have completed at least 3 years of collegiate or professional study leading to the qualifying degree for appointment may be called to active duty for the purpose of completing the requirements of § 21.25(a)(3). An appointment made under this subpart shall be terminated upon the officer's failure to continue a full-time course of study or failure to meet the requirements of § 21.25(a)(3) within 18 months after entering on active duty.

[34 FR 706, Jan. 17, 1969. Redesignated at 44 FR 46846, Aug. 6, 1979]

§ 21.55 Appointment to higher grades; candidates exceptionally qualified in specialized fields.

Any candidate eligible for examination for appointment in the grade of assistant pursuant to § 21.26 who, upon examination for such purpose, is found exceptionally qualified for the performance of duties requiring highly specialized training or experience may be recommended for appointment in the Reserve Corps in any grade up to and including the director grade without regard to the additional years of postgraduate training or experience prescribed for grades above the assistant grade.

§ 21.56 Reappointment.

An officer of the Reserve Corps, after being examined and found qualified for reappointment, may be recommended for reappointment to the same grade in the event that his commission expires before he becomes eligible for reappointment to a higher grade, or may be recommended for reappointment to a higher grade to be effective on or after the date on which he meets the qualifications prescribed in this subpart for original appointment to such higher grade.

§ 21.57 Examination for reappointment.

The examination of an officer of the Reserve Corps on active duty who is being considered for reappointment in such corps shall consist of a review and evaluation of his record with the Service. The examination of an officer of the Reserve Corps on inactive duty who is being considered for reappointment in such corps shall consist of (a) a review and evaluation of his record with the Service while on active duty, if any, and (b) the record of his training or experience during the period of his inactive duty preceding such examination. In the discretion of the Surgeon General the examination for reappointment of an officer, whether on active or inactive duty, may include an oral interview.

§ 21.58 Physical examination for reappointment.

Every officer of the Reserve Corps being considered for reappointment shall undergo such physical examination as the Surgeon General may direct. An officer on active duty may be recommended for reappointment unless he is found to have a physical disability which is determined to render him physically unfit to perform the duties of his office under section 402 of the Career Compensation Act of 1949, as amended. An officer may be recommended for promotion only if he meets the physical qualifications for original appointment. If an officer is not available to be physically examined because of circumstances which make it impracticable for the Service to require such examination, he may, in the discretion of the Surgeon General, be reappointed without such examination, but shall be examined as soon thereafter as practicable and his physical qualification or disqualification for continued or future active service shall be determined on the same basis as if the physical examination had been given prior to reappointment.

PART 22—PERSONNEL OTHER THAN COMMISSIONED OFFICERS

LEPROSY DUTY BY CIVIL SERVICE OFFICERS AND EMPLOYEES

Sec.
22.1 Duty requiring intimate contact with leprosy patients; additional pay for civil service officers or employees.

SPECIAL CONSULTANTS

22.3 Appointment of special consultants.
22.5 Leave without pay while on detail.

LEPROSY DUTY BY CIVIL SERVICE OFFICERS AND EMPLOYEES

§ 22.1 Duty requiring intimate contact with leprosy patients; additional pay for civil service officers or employees.

Every civil service officer or employee of the Service assigned to full-time duty for a period of 30 days or more at a station of the Service devoted to the care of leprosy patients shall receive, while so assigned, in addition to the basic compensation provided by law for his position, a sum equal to 25 per centum of such compensation: *Provided*, That the rate of total basic and additional compensation received by any such civil service officer or employee on June 30, 1952, under laws and regulations then in effect shall not, so long as the officer or employee remains on continuous assignment to such duty, be reduced prior to July 1, 1957, by reason of the foregoing provisions of this section.

(Sec. 209(g), 58 Stat. 687, as amended; 42 U.S.C. 210(e))

[21 FR 9821, Dec. 12, 1956]

SPECIAL CONSULTANTS

§ 22.3 Appointment of special consultants.

(a) When the Public Health Service requires the services of consultants who cannot be obtained when needed through regular Civil Service appointment or under the compensation provisions of the Classification Act of 1949, special consultants to assist and advise in the operations of the Service may be appointed, subject to the provisions of the following paragraphs and in accordance with such instructions as may be issued from time to time by the Secretary of Health and Human Services.

(b) Appointments, pursuant to the provisions of this section, may be made by those officials of the Service to whom authority has been delegated by the Secretary or his designee.

(c) The per diem or other rates of compensation shall be fixed by the appointing officer in accordance with criteria established by the Surgeon General.

(Sec. 208(c), 58 Stat. 686, as amended; 42 U.S.C. 209(e); sec. 207(f), 58 Stat. 686 as amended by 62 Stat. 40; 42 U.S.C. 209(f))

[21 FR 9821, Dec. 12, 1956, as amended at 31 FR 12939, Oct. 5, 1966]

§ 22.5 Leave without pay while on detail.

The Secretary or his delegate may, pursuant to section 214(d) of the Public Health Service Act, 42 U.S.C. 215(d), and with the consent of the officer or employee concerned, arrange, through agreements or otherwise, for a civilian officer or employee of the Public Health Service to be placed on leave without pay for the period of a detail to a State, a subdivision thereof, or a private non-profit institution and be paid by the non-Federal organization. Such an arrangement may be for a period of not to exceed 2 years, but may be extended for additional periods of not to exceed 2 years each.

(Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216)

[33 FR 18981, Dec. 20, 1968]

PART 23—NATIONAL HEALTH SERVICE CORPS

Subpart A—Assignment of National Health Service Corps Personnel

Sec.
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23.10 Under what circumstances may a National Health Service Corps site's reimbursement obligation to the Federal Government be waived?
23.11 Under what circumstances may the Secretary sell equipment or other property of the United States used by the National Health Service Corps site?
23.12 Who will supervise and control the assigned personnel?
23.13 What nondiscrimination requirements apply to National Health Service Corps sites?

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690 as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 333 *et seq.* of the Public

Health Service Act, 90 Stat. 2272 (42 U.S.C. 254f).

SOURCE: 45 FR 12790, Feb. 27, 1980, unless otherwise noted.

Subpart A—Assignment of National Health Service Corps Personnel

§ 23.1 To what entities does this regulation apply?

This regulation applies to the assignment of National Health Service Corps personnel under section 333 *et seq.* of the Public Health Service Act (42 U.S.C. 254f) to provide health services in or to health manpower shortage areas as designated under section 332 of the Public Health Service Act (42 U.S.C. 254e).

§ 23.2 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Assigned National Health Service Corps personnel" or "Corps personnel" means health personnel of the Regular and Reserve Corps of the Public Health Service Commissioned Corps and civilian personnel as designated by the Secretary including, but not limited to, physicians, dentists, nurses, and other health professions personnel who are assigned under section 333 of the Act and this regulation.

"Health manpower shortage area" means the geographic area, the population group, the public or nonprofit private medical facility or any other public facility which has been determined by the Secretary to have a shortage of health manpower under section 332 of the Act and its implementing regulation (42 CFR Part 5).

"National Health Service Corps site" means the entity to which personnel have been assigned under section 333 of the Act and this regulation to provide health services in or to health manpower shortage area.

"Nonprofit private entity" means as entity which may not lawfully hold or use any part of its net earnings to the benefit of any private shareholder or individual and which does not hold or use its net earnings for that purpose.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of that Department to whom the authority involved has been delegated.

§ 23.3 What entities are eligible to apply for assignment?

Any public or nonprofit private entity which is located in a health manpower shortage area, or has a demonstrated interest in the shortage area, may apply for the assignment of National Health Service Corps personnel.

§ 23.4 How must an entity apply for assignment?

(a) An application for the assignment of National Health Service Corps personnel must be submitted to the Secretary by an eligibe applicant in the form and at the time prescribed by the Secretary.[1] The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by law, the Act, this regulation, and any additional conditions of assignment imposed under these authorities.

(b) In addition to other pertinent information required by the Secretary, an application for the assignment of Corps personnel must include—

(1) A description of the applicant's overall organizational structure;

(2) A justification of the request for the assignment of personnel based upon the needs of the health manpower shortage area;

(3) A description of the applicant's financial plan for operating the National Health Service Corps site including a proposed budget, sources of non-Federal support obtained, and the proposed expenditures for obtaining adequate support staff, equipment and supplies;

(4) A list of the proposed fees and discounted fees to be charged for the provision of health services; and

(5) A request for an interest-free loan (not to exceed $50,000) sought under section 335(c) of the Act to assist the applicant in establishing the

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[1] Applications and instructions may be obtained from Regional Offices of the Department of Health and Human Services at the addresses set forth at 45 CFR 5.31(b).

practice of the assigned National Health Service Corps personnel, including a detailed justification of the amount requested.

(c) An application for assignment must include evidence that the applicant has provided a copy of the completed application for review to (1) each health systems agency designated under section 1515 of the Act for the health service area which includes all or part of the health manpower shortage area for which as assignment of National Health Service Corps personnel is sought or (2) if no health systems agency has been designated for such a health service area, to each State health planning and development agency designated under section 1521 of the Act for each State which includes all or part of the health manpower shortage area for which an assignment of National Health Service Corps personnel is sought.

(d) If an application for assignment is filed by an applicant which had previously been assigned National Health Service Corps personnel under an agreement entered into under section 329 of the Act as in effect before October 1, 1977, or under section 334 of the Act, the applicant must provide the information the Secretary, considers necessary to make the determinations required by section 333(a)(1)(D) of the Act.

§ 23.5 What are the criteria for deciding which applications for assignment will be approved?

(a) In approving or disapproving an application for assignment of Corps personnel, the Secretary will consider, among other pertinent factors:

(1) The applicant's ability and plans to meet the operational requirements in § 23.8.

(2) The administrative and managerial capability of the applicant.

(3) The soundness of the applicant's financial plan for operating the National Health Service Corps site.

(4) The extent to which community resources will be used in operating the National Health Service Corps site.

(5) Comments received from any designated health systems agency or any designated State health planning and development agency to which an application was submitted for review under § 23.4(c).

(6) Comments received from health professional societies serving the health manpower shortage area.

(b) Special consideration for the assignment of Corps personnel will be given to the entity which is located in a health manpower shortage area over an entity which is not located in a health manpower shortage area but has a demonstrated interest in it.

§ 23.6 What are the criteria for determining the entities to which National Health Service Corps personnel will be assigned?

(a) The Secretary may, upon approving an application for the assignment of personnel and after entering into an agreement with an applicant under § 23.7, assign National Health Service Corps personnel to provide health services in or to a health manpower shortage area.

(b) In assigning National Health Service Corps personnel to serve in a health manpower shortage area, the Secretary will seek to assign personnel who have those characteristics which will increase the probability of their remaining to serve in the health manpower shortage area upon completion of the period of assignment. In addition, the Secretary will apply a weighted-value system in which the first factor listed below is assigned the greatest weight and the second, third, and fourth factors are assigned lesser weights in descending order:

(1) The need of the health manpower shortage area as determined by criteria established under section 332(b) of the Act.

(2) The provision in the application for the use of physician assistants, nurse practitioners, or expanded function dental auxiliaries.

(3) The willingness of individuals, government agencies, or health entities within the health manpower shortage area to cooperate with the National Health Service Corps in providing effective health services.

(4) The comments of health professional societies serving the health manpower shortage area.

The values assigned to each of these criteria will be published in the FEDERAL REGISTER on an annual basis.

§ 23.7 What must an entity agree to do before the assignment is made?

(a) *Requirements.* To carry out the purposes of section 334 of the Act, each National Health Service Corps site must enter into an agreement with the Secretary under which the site agrees to:

(1) Be responsible for charging for health services provided by assigned National Health Service Corps personnel;

(2) Take reasonable action for the collection of the charges for those health services;

(3) Reimburse the United States the sums required under section 334(a)(3) of the Act; and

(4) Prepare and submit an annual report. The agreement will set forth the period of assignment (not to exceed 4 years), the number and type of Corps personnel to be assigned to the site, and other requirements which the Secretary determines necessary to carry out the purposes of the Act.

(b) *Termination.* An agreement entered into under this section may be terminated by either party on 30-days written notice or modified by mutual consent consistent with section 333 of the Act.

§ 23.8 What operational requirements apply to an entity to which National Health Service Corps personnel are assigned?

Each National Health Service Corps site must:

(a) Operate a health care delivery system within a planned or existing community structure to assure:

(1) The provision of high quality comprehensive health care;

(2) To the extent feasible, full professional health care coverage for the health manpower shortage area;

(3) Continuum of care, and

(4) The availability and accessibility of secondary and tertiary health care (the two more sophisticated levels of health care beyond primary care);

(b) Establish and maintain a patient record system;

(c) Implement a system for maintaining the confidentiality of patient records;

(d) Meet the requirements of applicable fire and safety codes;

(e) Develop, to the extent feasible, linkages with other health care facilities for the provision of services which supplement or complement the services furnished by the assigned Corps personnel;

(f) Operate a quality assurance system which meets the requirements of 42 CFR 51c.303(c) for the establishment and operation of a quality assurance system in a community health center; and

(g) Establish basic data, cost accounting, and management information and reporting systems as prescribed by the Secretary.

§ 23.9 What must an entity to which National Health Service Corps personnel are assigned (i.e., a National Health Service Corps site) charge for the provision of health services by assigned personnel?

(a) Except as provided in paragraph (b) of this section, individuals receiving services from assigned National Health Service Corps personnel must be charged on a fee-for-service or other basis at a rate which is computed to permit recovery of the value of the services and is approved by the Secretary.

(b) In determining whether to approve fees to be charged for health services, the Secretary will consider: The costs to the National Health Service Corps of providing the health services; the costs to the health manpower shortage area for providing the services; and the charges for similar services by other practitioners or facilities in or nearby the health manpower shortage area. However, if assigned National Health Service Corps personnel are providing services within the framework of an established health services delivery system, the Secretary may approve the fees charged under that system without regard to the foregoing factors.

(c)(1) No charge or a nominal charge will be made for health services provided by assigned National Health

Service Corps personnel to individuals within the health manpower shortage area with annual incomes at or below the "CSA Income Poverty Guidelines" (45 CFR 1060.2). However, no individual will be denied health services based upon inability to pay for the services. Any individual who has an annual income above the "CSA Income Poverty Guidelines," but whose income does not exceed 200 percent of the CSA levels, will receive health services at a nominal charge. However, charges will be made for services to the extent that payment will be made by a third party which is authorized or under legal obligation to pay the charges.

(2) The provisions of this paragraph also apply with respect to services provided by an individual who is fulfilling an NHSC scholarship obligation under section 753 or who received a special grant under section 755.

§ 23.10 Under what circumstances may a National Health Service Corps site's reimbursement obligation to the Federal Government be waived?

(a) The Secretary may waive in whole or in part the reimbursement requirements of section 334 of the Act if he determines that:

(1) The National Health Service Corps site is financially unable to meet the reimbursement requirements or that compliance with those requirements will unreasonably limit the ability of the site to adequately support the provision of services by assigned Corps personnel. In making these determinations, the Secretary will consider—

(i) The costs necessary to adequately support the health services provided by the assigned National Health Service Corps personnel and the income and financial resources available to meet the costs;

(ii) The ability of the applicant to obtain credit from suppliers, lending institutions, private organizations and individuals;

(iii) The need of the health manpower shortage area for health services; and

(iv) The extent to which the National Health Service Corps site utilizes health professions personnel.

(2) A significant percentage of the individuals who are located in the health manpower shortage area and are receiving the health services of the assigned National Health Service Corps personnel are elderly, living in poverty, or have other characteristics which indicate an inability to pay. For purposes of this section, "elderly" means persons 65 years or older and the "CSA Income Poverty Guidelines" will be used as the standard for determining whether individuals are living in poverty. Other characteristics indicating inability to pay include, but are not to be limited to, the ratio of unemployment in the health manpower shortage area and the area's cost-of-living index.

(b) Requests for waiver must be made at the time and in the manner and contain the documentation prescribed by the Secretary.

§ 23.11 Under what circumstances may the Secretary sell equipment or other property of the United States used by the National Health Service Corps site?

(a) Upon expiration of the assignment of all Corps personnel to a health manpower shortage area, the Secretary may sell equipment and other property of the United States used by the assigned personnel. The equipment may be sold at the fair market value or less than the fair market value to any entity providing health services in or to a health manpower shortage area if the Secretary determines that an entity is unable to pay the fair market value. In determining whether an entity is financially unable to purchase equipment or property at fair market value, the Secretary will consider (1) the present financial resources of the entity available to purchase the equipment or property based upon its current liabilities, and (2) the entity's ability to obtain the funds necessary to purchase the equipment or property. However, the Secretary will not sell the equipment or property for less than fair market value to a profitmaking organization unless the organization gives reasonable assurance that it will use the equipment or property to provide health services in or to the health manpower shortage area.

(b) The Secretary will give priority to sales to an entity providing reasonable assurance that it will use the equipment or property for the purpose of retaining within the health manpower shortage area National Health Service Corps personnel who have completed their assignments.

§ 23.12 Who will supervise and control the assigned personnel?

Assigned National Health Service Corps personnel will at all times remain under the direct supervision and control of the Secretary. Observance of institutional rules and regulations by the assigned personnel is a mere incident of the performance of their Federal functions and does not alter their direct professional and administrative responsibility to the Secretary.

§ 23.13 What nondiscrimination requirements apply to National Health Service Corps sites?

National Health Service Corps sites are advised that in addition to complying with the terms and conditions of this regulation, the following laws and regulations are applicable—

(a) Title VI of the Civil Rights Act of 1964 (43 U.S.C. 2000d *et seq.*) and its implementing regulations, 45 CFR Part 80 (prohibiting discrimination in federally assisted programs on the grounds of race, color, or national origin); and

(b) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and its implementing regulations, 45 CFR Part 84 (prohibiting discrimination in federally assisted programs on the basis of handicap).

(c) The Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*) and its implementing regulations, 45 CFR Part 90 (prohibiting unreasonable discrimination based on age in programs and activities receiving Federal financial assistance).

SUBCHAPTER C—MEDICAL CARE AND EXAMINATIONS

PART 31—MEDICAL CARE FOR CERTAIN PERSONNEL OF THE COAST GUARD, NATIONAL OCEAN SURVEY, PUBLIC HEALTH SERVICE, AND FORMER LIGHTHOUSE SERVICE

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31.13 Use of other than Service facilities.
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31.16 Retired personnel; extent of treatment.

SOURCE: 21 FR 9821, Dec. 12, 1956, unless otherwise noted.

DEFINITIONS

§ 31.1 Meaning of terms.

As used in this part, the term:

(a) "Act" means the Public Health Service Act, approved July 1, 1944, 58 Stat. 682, as amended.

(b) "Service" means the Public Health Service.

(c) "Surgeon General" means the Surgeon General of the Public Health Service.

(d) "Medical relief station" means a first-, second-, third-, or fourth-class station of the Service.

(e) "First-class stations" means a hospital operated by the Service.

(f) "Second-class station" means a medical relief facility, other than a hospital of the Service, under the charge of a commissioned officer.

(g) "Third-class station" means a medical relief facility, other than a hospital of the Service, under the charge of a medical officer or employee of the Service other than a commissioned officer.

(h) "Fourth-class station" means a medical relief facility designated by the Surgeon General, other than a first-, second-, or third-class station.

(i) "Designated physician" means a physician holding an appointment to act regularly for the Service for a class or classes of specified beneficiaries at a place where there is no medical relief station.

(j) "Designated dentist" means a dentist holding an appointment to perform dental service for the Service for a class or classes of specified beneficiaries.

(k) "Active duty" means active duty status as distinguished from being on inactive status or retired and includes periods of authorized leave or liberty.

(l) "Dependent members of families" in the case of male personnel means the lawful wife, the unmarried children (including stepchildren or adopted children) under 21 years of age, and the father or mother if in fact dependent upon such son for his or her chief support; and in the case of female personnel, the unmarried children (including stepchildren or adopted children) under 21 years of age if their father is dead or they are in fact dependent on such mother for their chief support, the father or mother if in fact dependent upon such daughter for his or her chief support, and the husband if in fact dependent upon such wife for his chief support: *Provided, however,* That in the case of members of the Women's Reserve of the Coast Guard the husbands of such members shall not be considered dependents.

(Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216)

PROVISIONS APPLICABLE TO COAST GUARD, NATIONAL OCEAN SURVEY AND PUBLIC HEALTH SERVICE

§ 31.2 Persons entitled to treatment.

To the extent and under the circumstances prescribed in §§ 31.2 to 31.10, the following persons shall be entitled to medical, surgical, and dental treatment and hospitalization by the Service:

(a) *Coast Guard.* (1) Commissioned officers, chief warrant officers, warrant officers, cadets, and enlisted personnel of the Regular Coast Guard, including those on shore duty and those on detached duty, whether on active duty or retired;

(2) Regular members of the Coast Guard Reserve when on active duty or when retired for disability;

(3) Temporary members of the Coast Guard Reserve when on active duty or in case of physical injury incurred or sickness or disease contracted while performing active Coast Guard duty;

(4) Members of the Women's Reserve of the Coast Guard when on active duty or when retired for disability;

(5) Members of the Coast Guard Auxiliary in case of physical injury incurred or sickness or disease contracted while performing active Coast Guard duty.

(b) *National Ocean Survey.* Commissioned officers, ships' officers, and members of the crews of vessels of the National Ocean Survey, including those on shore duty and those on detached duty whether on active duty or retired.

(c) *Public Health Service.* (1) Commissioned officers of the Regular Corps of the Service, whether on active duty or retired;

(2) Commissioned officers of the Reserve Corps of the Service when on active duty or when retired for disability.

(Sec. 326, 58 Stat. 697, as amended 42 U.S.C. 253)

§ 31.3 Use of Service facilities.

Except as otherwise provided in §§ 31.3 to 31.10, the persons specified in § 31.2 shall be entitled to medical, surgical, and dental treatment and hospitalization only at medical relief stations and by designated physicians and designated dentists, and the cost of services procured elsewhere shall not be borne by the Service.

(Sec. 326, 58 Stat. 697, as amended 42 U.S.C. 253)

§ 31.4 Use of other than Service facilities.

(a) When a person specified in § 31.2 who is on active duty requires immediate medical, surgical, or dental treatment or hospitalization and the urgency of the situation does not permit treatment at a medical relief station or by a designated physician or designated dentist, an officer of the same service as the patient may arrange for treatment or hospitalization at the expense of the Service.

(b) When the circumstances are such that an officer of the same service as the patient is not available to make the necessary arrangements, the treatment or hospitalization may be obtained by or on behalf of the patient at the expense of the Service.

(c) In every case of treatment or hospitalization as defined in paragraph (b) of this section, the responsible superior officer of the patient shall be notified as promptly as possible and a full report shall be submitted by such officer to the Surgeon General through appropriate official channels. As soon as practicable, unless the interests of the patient or the Government require otherwise, treatment or hospitalization shall be continued at a medical relief station or by a designated physician or designated dentist or at another appropriate Federal medical facility.

(d) When the necessary medical relief cannot be obtained from a medical relief station or a designated physician or designated dentist, preference shall be given to other Federal medical facilities when reasonably available and when conditions permit.

(e) Vouchers on proper forms covering expenses for treatment or hospitalization under the circumstances specified in paragraphs (a) and (b) of this section shall be forwarded to the Surgeon General through appropriate official channels. Each such voucher shall be accompanied by or contain a statement of the facts necessitating the treatment or hospitalization. Unreasonable charges for emergency treatment or hospitalization will not be allowed.

(f) Expenses for consultants or special services, or for dental treatment other than emergency measures to relieve pain, shall not be allowed except when authorized in advance by the headquarters of the Service or, in extraordinary cases, when subsequently approved by such headquarters upon receipt of report and satisfactory explanation as to the necessity and urgency therefor.

(Sec. 326, 58 Stat. 697, as amended; 42 U.S.C. 253)

§ 31.5 Application for treatment; active duty personnel.

(a) An applicant for medical relief who is on active duty shall furnish a certificate identifying him. Such certificate, in the case of Coast Guard personnel, shall be signed by an officer of the Coast Guard, and in the case of National Ocean Survey personnel, shall be signed by an officer of the National Ocean Survey. Commissioned officers of any of the services mentioned in § 31.2 and officers in charge of units may sign their own certificates. In an emergency, the officer in charge of a medical relief station, or a designated physician or designated dentist, may accept other evidence of status satisfactory to him.

(b) A temporary member of the Coast Guard Reserve except when on active duty or a member of the Coast Guard Auxiliary shall, when applying for medical relief, furnish a statement signed by a responsible superior officer setting forth the facts and circumstances giving rise to the need for medical relief. In emergencies, such statement shall be furnished promptly after the member has received the immediately required care and treatment. Such statement shall be presumptive evidence of the facts stated, but if investigation indicates that the injury, sickness, or disease was not incurred or contracted in the manner stated, further treatment may be denied.

(Sec. 326, 58 Stat. 697, as amended; 42 U.S.C. 253)

§ 31.6 Personnel absent without leave.

No member of any of the services enumerated in § 31.2 shall be entitled when absent without leave to medical relief except at a medical relief station or by a designated physician or designated dentist.

(Sec. 326, 58 Stat. 697, as amended; 42 U.S.C. 253)

§ 31.7 Continuance of medical relief after loss of status.

If a member is separated from any of the services enumerated in § 31.2, except persons specified in § 31.2(a) (3) and (5) who shall be entitled to treatment after separation under the conditions set forth in such paragraphs, while undergoing treatment by the Service, his treatment shall be discontinued immediately unless the physician in charge determines that the condition of the patient does not permit interruption of treatment, in which case the treatment shall be discontinued as soon as practicable and the condition of the patient permits. At that time he shall be discharged from treatment and shall not thereafter be afforded medical relief by the Service by reason of his previous service.

(Sec. 326, 58 Stat. 697, as amended; 42 U.S.C. 253)

§ 31.8 Retired personnel; extent of treatment.

(a) A retired member of the Coast Guard, National Ocean Survey, or Public Health Service specified in § 31.2 shall be entitled to medical, surgical, and dental treatment and hospitalization at medical relief stations of the first-, second-, and third-class, upon presentation of satisfactory evidence of his status.

(b) Elective medical or surgical treatment requiring hospitalization shall be furnished only at hospitals operated by the Service.

(c) Dental treatment shall be furnished to the extent of available facilities only at medical relief stations where full-time dental officers are on duty; at other medical relief stations the dental treatment shall be limited to emergency measures necessary to relieve pain.

(Sec. 326, 58 Stat. 697, as amended; 42 U.S.C. 253)

§ 31.9 Dependent members of families; treatment.

To the extent and under the circumstances prescribed in this part, the Service shall provide medical advice and outpatient treatment at first-, second-, and third-class medical relief stations and hospitalization at first-class stations to the dependent members of families of the following persons:

(a) *Coast Guard.* Commissioned officers, chief warrant officers, warrant officers, cadets, and enlisted personnel of the Regular Coast Guard, including those on shore duty and those on detached duty, whether on active duty or retired; and regular members of the United States Coast Guard Reserve and members of the Women's Reserve of the Coast Guard, when on active duty or when retired for disability.

(b) *National Ocean Survey.* Commissioned officers, ships' officers, and members of the crews of vessels of the United States National Ocean Survey, including those on shore duty and those on detached duty, whether on active duty or retired.

(c) *Public Health Service.* Commissioned officers of the Regular Corps of the Service, whether on active duty or retired, and commissioned officers of the Reserve Corps of the Service when on active duty or when retired for disability.

(Sec. 326, 58 Stat. 697, as amended; 42 U.S.C. 253)

§ 31.10 Dependent members of families; use of Service facilities.

(a) A dependent member of the family of any person specified in § 31.9 shall, upon presentation of satisfactory evidence of such status, be entitled to medical advice and out-patient treatment at first-, second-, and third-class medical relief stations and hospitalization at first-class stations if suitable accommodations are available therein and if the condition of the dependent is such as to require hospitalization, both as determined by the medical officer in charge.

(b) Hospitalization at first-class stations shall be at a per diem cost to the officer, enlisted person, member of a crew or other person concerned. Such cost shall be at such uniform rate as may be prescribed from time to time by the President for the hospitalization of dependents of naval and Marine Corps personnel at any naval hospital.

(c) Hospitalization at first-class stations and out-patient treatment at first-, second-, and third-class stations may include such services and supplies as, in the judgment of the medical officer in charge, are necessary for reasonable and adequate treatment.

(d) Dental treatment shall be furnished to the extent of available facilities only at medical relief stations where full-time officers are on duty.

(Sec. 326, 58 Stat. 697, as amended; 42 U.S.C. 253)

PROVISIONS APPLICABLE TO PERSONNEL OF FORMER LIGHTHOUSE SERVICE

§ 31.11 Persons entitled to treatment.

To the extent and under the circumstances prescribed in this part, the following persons shall be entitled to medical, surgical, and dental treatment and hospitalization by the Service: Lightkeepers, assistant lightkeepers, and officers and crews of vessels of the former Lighthouse Service, including any such persons who subsequent to June 30, 1939, have involuntarily been assigned to other civilian duty in the Coast Guard, who were entitled to medical relief at hospitals and other stations of the Service prior to July 1, 1944, and who are now or hereafter on active duty or who have been or may hereafter be retired under the provisions of section 6 of the act of June 20, 1918, as amended (33 U.S.C. 763).

(Sec. 610(b), 58 Stat. 714, as amended; 33 U.S.C. 763c)

§ 31.12 Use of Service facilities.

Except as otherwise provided herein, the persons specified in § 31.11 shall be entitled to medical, surgical, and dental treatment and hospitalization only at medical relief stations and by designated physicians and designated dentists, and the cost of services procured elsewhere shall not be borne by the Service.

(Sec. 610(b), 58 Stat. 714, as amended; 33 U.S.C. 763c)

§ 31.13 Use of other than Service facilities.

(a) When a person specified in § 31.11 who is on active duty requires immediate medical, surgical, or dental treatment or hospitalization and the urgency of the situation does not permit treatment at a medical relief station or by a designated physician or designated dentist, an officer or other appropriate supervisory official of the Coast Guard may arrange for treatment or hospitalization.

(b) In every such case of treatment or hospitalization, a full report thereof shall be submitted to the Surgeon General through Coast Guard headquarters. As soon as practicable, unless the interests of the patient or the Government require otherwise, treatment or hospitalization shall be continued at a medical relief station or by a designated physician or designated dentist or at another appropriate Federal medical facility.

(c) When the necessary medical relief cannot be obtained from a medical relief station or a designated physician or designated dentist, preference shall be given to other Federal medical facilities when reasonably available and when conditions permit.

(d) Vouchers on proper forms covering expenses for treatment or hospitalization under the circumstances specified in paragraph (a) of this section shall be forwarded to the Surgeon General through Coast Guard headquarters. Each such voucher shall be accompanied by or contain a statement of the facts necessitating the treatment or hospitalization. Unreasonable charges for emergency treatment or hospitalization will not be allowed.

(e) Expenses for consultants or special services, or for dental treatment other than emergency measures to relieve pain, shall not be allowed except when authorized in advance by the headquarters of the Service or, in extraordinary cases, when subsequently approved by such headquarters upon receipt of report and satisfactory explanation as to the necessity and urgency therefor.

(Sec. 610(b), 58 Stat. 714 as amended; 33 U.S.C. 763c)

§ 31.14 Application for treatment; active duty personnel.

An applicant for medical relief who is on active duty shall furnish a certificate identifying him. Such certificate shall be signed by an officer or other appropriate supervisory official of the Coast Guard. In an emergency, the officer in charge of a medical relief station, or a designated physician or designated dentist, may accept other evidence of status satisfactory to him.

(Sec. 610(b), 58 Stat. 714 as amended; 33 U.S.C. 763c)

§ 31.15 Continuance of medical relief after loss of status.

If a person is separated while undergoing treatment by the Service, his treatment shall be discontinued immediately unless the physician or dentist in charge determines that the condition of the patient does not permit interruption of treatment, in which case the treatment shall be discontinued as soon as practicable and the condition of the patient permits. At that time he shall be discharged from treatment and shall not thereafter be afforded medical relief by the Service by reason of his previous service.

(Sec. 610(b), 58 Stat. 714, as amended; 33 U.S.C. 763c)

§ 31.16 Retired personnel; extent of treatment.

(a) Any retired person specified in § 31.11 shall be entitled to medical, surgical, and dental treatment and hospitalization at medical relief stations of the first, second, and third class, upon presentation of satisfactory evidence of his status.

(b) Elective medical or surgical treatment requiring hospitalization shall be furnished only at hospitals operated by the Service.

(c) Dental treatment shall be furnished to the extent of available facilities only at medical relief stations where full-time dental officers are on duty; at other medical relief stations the dental treatment shall be limited to emergency measures necessary to relieve pain.

(Sec. 610(b), 58 Stat. 714, as amended; 33 U.S.C. 763c)

PART 32—MEDICAL CARE FOR SEAMEN AND CERTAIN OTHER PERSONS

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32.106 Conditions and extent of treatment; rates; burial.

NONBENEFICIARIES; TEMPORARY TREATMENT IN EMERGENCY

32.111 Conditions and extent of treatment; charges.

AUTHORITY: Sec. 2, 321, 322, 58 Stat. 682, 695, 696 as amended (42 U.S.C. 2, 248, 249); Sec. 320(b), 58 Stat. 698, as amended (42 U.S.C. 247e(b)).

SOURCE: 40 FR 25816, June 19, 1975, unless otherwise noted.

DEFINITIONS

§ 32.1 Meaning of terms.

All terms not defined herein shall have the same meaning as given them in the Act.

(a) "Act" means the Public Health Service Act, approved July 1, 1944, 58 Stat. 682, as amended;

(b) "Service" means the Public Health Service;

(c) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may have been delegated.

(d) "Seamen" includes any person employed on board in the care, preservation, or navigation of any vessel, or in the service, on board, of those engaged in such care, preservation, or navigation, but does not include the owner or joint owners of a vessel or the spouse of any such owner, except owner-operators as described in § 32.6(a)(12);

(e) "Vessel" includes every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water, exclusive of aircraft and amphibious contrivances;

(f) "Authorizing Official" means Service officers or employees duly designated by the Director, Division of Hospitals and Clinics to authorize and provide care and treatment to beneficiaries at Service expense;

(g) "Active Duty," with respect to an enrollee of the United States Maritime

BEST DOCUMENT AVAILABLE

Service, means that the enrollee is on the active list of that service, as distinguished from being on inactive status, and includes absence on authorized leave or liberty;

(h) "Commercial fishing operations" means the gathering of any form of either fresh water or marine animal life for sale on a commercial basis through available markets.

BENEFICIARIES

§ 32.6 Persons eligible.

(a) Under this part the following persons are entitled to care and treatment by the Service as hereinafter prescribed:

(1) Seamen employed on vessels of the United States registered, enrolled, or licensed under the maritime laws thereof, other than canal boats engaged in the coasting trade, hereinafter designated as American seamen;

(2) Seamen employed on United States or foreign flag vessels as employees of the United States;

(3) Seamen, not enlisted or commissioned in the military or naval establishments, who are employed on State school ships or on vessels of the United States Government of more than five tons burden;

(4) Seamen on vessels of the Mississippi River Commission;

(5) Officers and crew members of vessels of the Fish and Wildlife Service;

(6) Enrollees in the United States Maritime Service on active duty and members of the Merchant Marine Cadet Corps;

(7) Cadets at State maritime academies or on State training ships;

(8) Seamen-trainees while participating in maritime training programs to develop or enhance their employability in the maritime industry;

(9) Persons afflicted with Hansen's disease;

(10) Seamen on foreign flag vessels other than those seamen employed on foreign flag vessels specified in paragraph (a)(2) of this section;

(11) Non-beneficiaries for temporary treatment and care in case of emergency;

(12) Persons who own vessels registered, enrolled, or licensed under the maritime laws of the United States, who are engaged in commercial fishing operations, and who accompany such vessels on such fishing operations, and a substantial part of whose services in connection with such fishing operations are comparable to services performed by seamen employed on such vessel or on vessels engaged in similar operations.

(b) Separate regulations govern: (1) The medical care of certain personnel, and their dependents, of the Coast Guard, National Oceanic and Atmospheric Administration and Public Health Service (see Part 31 of this chapter);

(2) Physical and mental examinations of aliens (see Part 34 of this chapter);

(3) Care and treatment of narcotic addicts (see Part 33 of this chapter); and

(4) Medical Care for Indians. (See Part 36 of this chapter.)

(c) While regulations of the Public Health Service are not required with respect thereto, circular instructions by the Service cover the care and treatment or physical examination of the following:

(1) Persons not otherwise eligible for treatment for purposes of study;

(2) Persons detained in accordance with quarantine laws;

(3) Persons detained by the Immigration and Naturalization Service, for treatment at the request of that Service;

(4) Persons entitled to treatment under the Federal Employees' Compensation Act and extensions thereof;

(5) Beneficiaries of other Federal agencies on a reimbursable basis;

(6) Medical examinations of;

(i) Employees of the Alaska Railroad and employees of the Federal Government for retirement purposes;

(ii) Employees in the Federal classified service, and applicants for appointment, as requested by the Civil Service Commission for the purpose of promoting health and efficiency;

(iii) Seamen for purposes of qualifying for certificates of service; and

(iv) Employees eligible for benefits under the Longshoremen's and Harbor Workers' Compensation Act, as amended as requested by any deputy commissioner thereunder.

AMERICAN SEAMEN

§ 32.11 Scope of benefits

American seamen (hereinafter referred to in §§ 32.11 to 32.23, inclusive, as seamen) shall, on presenting evidence of eligibility, be entitled to medical, surgical, and dental treatment or hospitalization at medical care facilities operated by the Service. Depending upon the availability of funds and other management considerations, health care and services from non-Service providers and at non-Service facilities may be arranged for and authorized at the expense of the Service upon such terms and conditions as the Secretary or his designee may from time to time announce by publication of a notice in the FEDERAL REGISTER.

[46 FR 25624, May 8, 1981]

§§ 32.12–32.13 [Reserved]

§ 32.14 Evidence of eligibility.

(a) As evidence of his eligibility a seaman must present a properly executed master's certificate, or a continuous discharge book, or a certificate of discharge, showing that he has been employed on a registered, enrolled, or licensed vessel of the United States. The certificate of the owner or accredited commercial agent of a vessel as to the facts of the employment of any seaman on said vessel may be accepted in lieu of the master's certificate where the latter is not procurable. When an applicant cannot furnish any of the foregoing documents, his certification as to the facts of his most recent (including his last) employment as a seaman, stating names of vessels and dates of service, may be accepted as evidence in support of his eligibility. Documentary evidence of eligibility, excepting continuous discharge books and certificates of discharge, shall be filed at the medical care facility of the Service where application is made. Where continuous discharge books and certificates of discharge are submitted as evidence of eligibility, the pertinent information shall be abstracted therefrom, certified by the officer accepting the application, and filed at the station.

(b) Except as otherwise provided in §§ 32.11 to 32.23, inclusive, documentary evidence of eligibility must show that the applicant has been employed for 60 days of continuous service on a registered, enrolled, or licensed vessel of the United States, a part of which time must have been during the 180 days immediately preceding application for relief. There may be included as a part of such 60 days of continuous service as a seaman time spent in training as (1) an active duty enrollee in the United States Maritime Service, (2) a member of the Merchant Marine Cadet Corps, (3) a cadet at a State maritime academy, or (4) a cadet on a State training ship. The phrase "60 days of continuous service" shall not be held to exclude seamen whose papers show brief intermissions between short services that aggregate the required 60 days: *Provided*, That any such intermission does not exceed 60 days. The time during which a seaman has been treated as a patient of the Service shall not be considered as absence from the vessel in determining eligibility. When the seamen's service on his last vessel is less than 60 days, his oath or affirmation as to previous service may be accepted.

§ 32.15 Sickness or injury while employed.

A seaman taken sick or injured on board or ashore when actually employed on a vessel shall be entitled to care and treatment without regard to length of service.

§ 32.16 Seamen from wrecked vessels.

Seamen taken from wrecked vessels of the United States and returned to the United States, if sick or disabled at the time of their arrival in the United States, shall be entitled to care and treatment without regard to length of service.

§ 32.17 Lapse of more than 180 days since last service.

(a) Where more than 180 days have elapsed since an applicant's last service as a seaman, he will no longer be eligible for benefits from the Service: *Provided*, That if he can show that he has not definitely changed his occupation, such period of time shall not exclude him from receiving care and treatment (1) if due in whole or in part to closure of navigation or economic conditions resulting in decreased shipping with consequent lack of opportunity to ship; or (2) if he provides satisfactory evidence that he has been under continuous medical supervision and treatment at other than Service expense for a condition which occurred or arose during any period of treatment at a Service facility or at Service expense.

(b) Where a seaman receives care and treatment by the Service or at Service expense during a period of eligibility for a condition or illness which requires, in the opinion of the attending physician, continuing and recurring care and treatment on a regular and frequent basis, such periods of continuing and recurring care and treatment whether obtained privately by the seaman or at Service facilities or Service expense shall not be included in the computation of the 180 day period above.

§ 32.18 Procedure in case of doubtful eligibility.

When a reasonable doubt exists as to the eligibility of an applicant for service, the matter shall be referred immediately to the appropriate authorizing official or Hospital Director for decision. If, in the opinion of such person the applicant's condition is such that immediate care and treatment is necessary, temporary care and treatment shall be given pending the decision as to eligibility.

§ 32.19 False document evidencing service.

The issue or presentation of a false document as evidence of service with intent to procure the treatment of a person as a seaman shall be immediately reported to the Headquarters of the Service.

§ 32.20 Treatment during voyage.

The Service shall not be liable for expenses incurred during a voyage for the care of sick and disabled seamen.

§ 32.21 Care while in custody.

Seamen shall not be provided treatment at the expense of the Service while in police custody.

§ 32.22 Reconsideration of eligibility denial.

A decision of the authorizing official or Hospital Director denying eligibility shall be communicated to the seaman in writing, shall set forth the reasons therefore, and shall state that such decision may be reconsidered by the Secretary upon written request setting forth the facts in support of such request.

§ 32.23 Certificate of discharge from treatment.

A certificate of discharge from treatment may, at the discretion of the officer in charge, be given to a hospital patient, but such certificate, when presented at another medical care facility shall not be taken as establishing the seaman's eligibility for further care and treatment, but may be considered in connection with other documentary evidence of eligibility submitted by the seaman.

SEAMEN; STATE SCHOOL SHIPS AND VESSELS OF THE UNITED STATES GOVERNMENT

§ 32.46 Conditions and extent of treatment.

Seamen, not enlisted or commissioned in the military or naval establishments, who are employed on State school ships, on vessels of the United States Government of more than five tons burden, or on vessels of the Mississippi River Commission or of the Fish and Wildlife Service, shall be entitled to care and treatment by the Service under the same conditions, where applicable, and to the same extent as is provided for American seamen.

OWNER-OPERATORS OF COMMERCIAL FISHING VESSELS

§ 32.57 Conditions and extent of treatment.

Persons who own vessels registered, enrolled, or licensed under the maritime laws of the United States, who are engaged in commercial fishing operations, and who accompany such vessels on such fishing operations, and a substantial part of whose services in connection with such fishing operations are comparable to services performed by seamen employed on such vessel or on vessels engaged in similar operations shall be entitled to care and treatment by the Service under the same conditions, where applicable, and to the same extent as is provided for American seamen.

MARITIME SERVICE ENROLLEES AND MERCHANT MARINE CADETS

§ 32.61 Use of Service facilities.

(a) Enrollees in the United States Maritime Service on active duty and members of the Merchant Cadet Corps shall, upon written request of the responsible officer of the station or training ship to which such enrollees or cadets are attached, identifying the applicant, be entitled to medical surgical, and dental treatment or hospitalization at medical care facilities of the Service or at Service expense. Whenever an enrollee or cadet applies for care without the above-mentioned written request and in the opinion of the responsible Service officer the applicant's condition is such that immediate care and treatment is necessary, temporary care and treatment shall be given pending verification of the applicant's status as an enrollee or cadet.

(b) If eligibility cannot be established at the time of application by the enrollee or cadet or by the person who applies in his behalf, the applicant shall be notified that the authorization for treatment is conditional and that the payment of reasonable expenses by the Service for such treatment shall be subject to proof of eligibility.

(c) The authorizing official shall keep himself informed regarding the progress of the case in order that treatment or hospitalization shall not be unnecessarily prolonged.

§ 32.62 Injury while in custody.

Enrollees on active duty or cadets shall not be provided treatment at the expense of the Service while in police custody.

§ 32.63 Absence without leave.

Enrollees on active duty or cadets shall not be entitled, when absent without leave, to receive medical care except at a medical care facility of the Service or under contract to the Service.

CADETS AT STATE MARITIME ACADEMIES OR ON STATE TRAINING SHIPS

§ 32.76 Conditions and extent of treatment.

Cadets at State maritime academies or on State training ships shall be entitled to care and treatment by the Service under the same conditions and to the same extent as is provided for American seamen. *Provided, however,* That the written request of the superintendent or other responsible officer of an academy, including the master of a training ship, shall be accepted in lieu of the documentary evidence of eligibility required of American seamen.

PERSONS WITH HANSEN'S DISEASE

AUTHORITY: Sec. 331 and 332, 58 Stat. 696, 698 as amended; 42 U.S. C. 255, 256.

§ 32.86 Admissions to Service facilities.

Any person with Hansen's disease who presents himself for care or treatment or who is referred to the Service by the proper health authority of any State, Territory, or the District of Columbia shall be received into the Service hospital at Carville, Louisiana, or into any other hospital of the Service which has been designated by the Secretary as being suitable for the accommodation of persons with Hansen's disease.

§ 32.87 Confirmation of diagnosis.

At the earliest practicable date, after the arrival of a patient at the Service hospital at Carville, Louisiana, or at another hospital of the Service the medical staff shall confirm or disprove the diagnosis of Hansen's disease. If the diagnosis of Hansen's disease is confirmed, the patient shall be provided appropriate inpatient or outpatient treatment. If the diagnosis is not confirmed, the patient shall be discharged.

[40 FR 25816, June 19, 1975; 40 FR 36774, Aug. 22, 1975]

§ 32.88 Examinations and treatment.

Patients will be provided necessary clinical examinations which may be required for the diagnosis of primary or secondary conditions, and such treatment as may be prescribed.

§ 32.89 Discharge.

Patients with Hansen's disease will be discharged when, in the opinion of the medical staff of the hospital, optimum hospital benefits have been received.

§ 32.90 Notification to health authorities regarding discharged patients.

Upon the discharge of a patient the medical officer in charge shall give notification of such discharge to the appropriate health officer of the State, Territory, or other jurisdiction in which the discharged patient is to reside. The notification shall also set forth the clinical findings and other essential facts necessary to be known by the health officer relative to such discharged patient.

§ 32.91 Purchase of Services for Hansen's Disease Patients.

Hansen's disease patients being treated on either an inpatient or outpatient basis at a hospital or clinic facility of the Service, other than the National Center for Hansen's Disease (Carville, Louisiana), may, at the sole discretion of the Secretary and subject to available appropriations, be provided care for the treatment of Hansen's disease at the expense of the Service upon closure or transfer of such hospital or clinic pursuant to section 987 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35). Payment will only be made for care arranged for by an authorizing official of the Service as defined in § 32.1(f) of this part.

[46 FR 51918, Oct. 23, 1981]

SEAMEN ON FOREIGN FLAG VESSELS

§ 32.106 Conditions and extent of treatment; rates; burial.

(a) Seamen on foreign flag vessels may, when suitable accommodations are available and on application of the master, owner, or agent of the vessel, be provided treatment at medical care facilities of the Service at rates prescribed by the Secretary.

(b) Upon application, the Service may assist in arranging for private hospitalization of such seamen or private services in connection with their treatment at the expense of the master, owner, or agent of the vessel.

(c) If any such seaman dies while receiving treatment by the Service, the expenses of burial shall be paid directly to the vendors by the master, owner, or agent.

NONBENEFICIARIES: TEMPORARY TREATMENT IN EMERGENCY

§ 32.111 Conditions and extent of treatment; charges.

(a) Persons not entitled to treatment by the Service may be provided temporary care and treatment at medical care facilities of the Service in case of emergency as an act of humanity.

(b) Persons referred to in paragraph (a) of this section who, as determined by the officer in charge of the Service facility, are able to defray the cost of their care and treatment shall be charged for such care and treatment at the following rates (which shall be deemed to constitute the entire charge in each instance): In the case of hospitalization, at the current interdepartmental reciprocal per diem rate; and, in the case of outpatient treatment, at rates established by the Secretary.

PART 34—MEDICAL EXAMINATION OF ALIENS

Sec.
34.1 Applicability.
34.2 Definitions.
34.3 Examinations; female aliens.
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34.7 Certificates and notifications; Class A.
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34.10 Certificates and notifications; Class C.
34.11 Deferral of examinations; adequacy of facilities.
34.12 Applicability of Foreign Quarantine Regulations.
34.13 Medical and other care; death.
34.14 Reexamination; convening of boards; expert witnesses; reports.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, sec. 234, 66 Stat. 198; 42 U.S.C. 216, 8 U.S.C. 1224; sec. 322, 325, 58 Stat. 696, as amended 697, as amended, secs. 212, 326, 66 Stat. 182, as amended 200; 42 U.S.C. 249, 252, 8 U.S.C. 1182, 1226.

SOURCE: 21 FR 9829, Dec. 12, 1956, unless otherwise noted.

§ 34.1 Applicability.

The provisions of this part shall apply to:

(a) The medical examination of (1) aliens applying for a visa at a consulate of the United States, (2) aliens arriving in the United States, and (3) aliens presented or referred by the Immigration Service in connection with determination of their admissibility into the United States, and

(b) The medical and other care, and burial, of aliens admitted to Public Health Service stations and hospitals at the request of the Immigration Service.

§ 34.2 Definitions.

As used in this part, terms shall have the following meanings:

(a) *Immigration Service.* The Immigration and Naturalization Service of the Department of Justice.

(b) *Dangerous contagious disease.* Any of the following diseases:

(1) Chancroid.
(2) Gonorrhea.
(3) Granuloma inguinale.
(4) Leprosy, infectious.
(5) Lymphogranuloma venereum.
(6) Syphilis, infectious stage.
(7) Tuberculosis, active.

(c) *Medical certificate.* A document issued to the Immigration Service by a medical examiner, reporting the presence of any physical or mental defect, disease, or disability, or the previous occurrence of one or more attacks of insanity, in an alien.

(d) *Medical notification.* A document issued to a consular authority by a medical examiner, reporting the presence of any physical or mental defect, disease, or disability or the previous occurrence of one or more attacks of insanity, in an alien. Medical notification shall be made on the form prescribed for reporting the results of the medical examination of applicants for visas.

(e) *Medical officer.* A physician of the Public Health Service assigned or detailed by the Surgeon General of the Public Health Service to make mental and physical examinations of aliens.

(f) *Medical officer in charge.* A medical officer charged by the Surgeon General with responsibility for the conduct and supervision of all medical examinations made at a designated place or in a designated area.

[21 FR 9829, Dec. 12, 1956, as amended at 26 FR 9856, Oct. 20, 1961; 35 FR 15289, Oct. 1, 1970]

§ 34.3 Examinations; female aliens.

Female aliens shall be examined only in the presence of a female nurse or other female, or by a female physician.

§ 34.4 Scope of examinations.

(a) *General.* In performing examinations and reexaminations, medical examiners shall give consideration to only those matters that relate to the physical or mental condition of the alien and shall issue certificates or notifications of a defect, disease, or disability or previous occurrence of one or more attacks of insanity as hereinafter provided only if the presence of such defect, disease, or disability or previous occurrence of one or more attacks of insanity has been clearly established.

(1) *Persons subject to requirement for chest X-ray examination and serologic test.* Except as provided in paragraph (a)(2) of this section, a chest X-ray examination for tuberculosis and a serologic test for syphilis shall be required as part of the examination of:

(i) All applicants for immigrant visas;

(ii) All students and exchange visitors who are required by a consular authority to have a medical examination upon application for a nonimmigrant visa;

(iii) All other applicants for a nonimmigrant visa who are required by a consular authority to have a medical examination if such X-ray examination and serologic test are considered necessary by the medical examiner; and

(iv) All aliens outside the United States who apply for conditional entry and all aliens in the United States who apply for adjustment of status, under the immigration laws and regulations.

(2) *Exceptions.* Neither a chest X-ray examination nor a serologic test for syphilis shall be required if the alien is under the age of 15: *Provided,* That a tuberculin test may be required where there is evidence of contact with a known case of tuberculosis or other reason to suspect infection with tuberculosis and a chest X-ray examination required in the event of a positive reaction, and a serologic test where there is reason to suspect infection with syphilis. Additional exceptions to the requirement for a chest X-ray examination may be authorized for good cause upon application approved by the Director, Center for Disease Control, Health Services and Mental Health Administration.

(3) *How and where performed.* (i) All X-ray films used in medical examinations performed under the regulations in this part shall be at least 70 mm. in size. In case of abnormal findings in the lungs, a full-sized film (approximately 14 × 17 inches; 35.6 × 43.2 cm.) shall be used on which to base the diagnosis.

(ii) When necessary X-ray and laboratory facilities are not available to the medical examiner, the applicant shall furnish a chest X-ray film, a reading thereof, and a serologic test report in order that the medical examination may be completed. If X-ray or serologic test facilities necessary for the completion of the examination of a visa applicant or of an applicant for conditional entry are not available in the community where the examination is made, the medical examiner shall so state on the medical examination form and the procedures will be completed at the time of examination at the U.S. port of entry.

(iii) The X-ray reading and serologic test report shall be included in the medical examination report. When the medical examiner's conclusions are based on a study of more than one X-ray film, the medical examination report shall include at least a summary statement of findings in the earlier films, followed by a complete reading of the last film, and dates and details of any laboratory tests for tuberculosis.

(4) *Procedure for transmitting records.* For aliens issued immigrant visas, the medical examination report shall be placed in a separate envelope which shall be sealed and attached to the alien's visa in such a manner as to be readily detached by the medical examiner at the U.S. port of entry. The X-ray film shall be included in this envelope or, in the case of large films, shall be placed in a separate envelope which shall be sealed and given to the alien for presentation at the port of entry. For aliens issued nonimmigrant visas and for applicants for conditional entry, the medical examination report and the X-ray film shall be placed in an envelope which shall be sealed and given to the alien for presentation at the U.S. port of entry. When more than one X-ray film is used as a basis for the medical examiner's conclusions, all films shall be included. However, the X-ray film or films used in connection with the examination shall not be required to be attached to the visa or otherwise presented to the medical examiner at the U.S. port of entry when an exception to this requirement is authorized by the Director, Center for Disease Control, Health Services and Mental Health Administration.

(5) *Failure to present records.* If, on examination at the time determination of admissibility is to be made at the U.S. port of entry, no X-ray film or medical examination report, including X-ray reading and serologic test report, is presented in accordance with the provisions of this paragraph, a medical hold shall be issued pending

completion of any necessary examination procedures.

[21 FR 9829, Dec. 12, 1956, as amended at 30 FR 16112, Dec. 28, 1965; 37 FR 16937, Aug. 23, 1972]

§ 34.5 Aliens free of defect, disease, or disability.

If an alien is found to have no physical or mental defect, disease, or disability and no history of a previous attack of insanity, the medical examiner shall so indicate to the consular or immigration authority concerned.

§ 34.6 Aliens afflicted with defect, disease, or disability.

If an alien is found to have any physical or mental defect, disease, or disability or to have had one or more attacks of insanity, the medical examiner shall report his findings to the Immigration Service by medical certificate or to the consular authority by medical notification.

§ 34.7 Certificates and notifications; Class A.

A Class A certificate or Class A notification shall be issued with respect to aliens who:

(a) Are mentally retarded;

(b) Are insane;

(c) Have had one or more attacks of insanity;

(d) Are afflicted with psychopathic personality, sexual deviation, or a mental defect;

(e) Are narcotic drug addicts or chronic alcoholics;

(f) Are afflicted with any dangerous contagious disease: *Provided, however,* That a Class A certificate or Class A notification of a mental defect, disease, or disability shall in no case be issued with respect to an alien having only mental shortcomings due to ignorance, or suffering only from a mental condition (1) attributable to remediable physical causes or (2) of a temporary nature, caused by a toxin, drug, or disease.

[30 FR 16112, Dec. 28, 1965]

§ 34.8 Certificates and notifications; Class B.

A Class B certificate or Class B notification shall be issued with respect to an alien who has a physical defect, disease, or disability serious in degree or permanent in nature amounting to a substantial departure from normal physical well-being. The certificate, or notification, shall state the nature and extent of the defect; the degree to which the alien is incapable of normal physical activity; and the extent to which the condition is remediable.

§ 34.9 Class A or Class B certificates; helpless aliens.

If an alien with respect to whom a Class A or Class B certificate is issued is helpless from sickness, mental or physical disability, or infancy, the medical examiner shall so state in the certificate.

§ 34.10 Certificates and notifications; Class C.

A Class C certificate or Class C notification shall be issued with respect to an alien who has a defect, disease, or disability other than those for which a Class A or B certificate (or notification) is required to be issued.

§ 34.11 Deferral of examination; adequacy of facilities.

(a) Whenever, upon an examination, it appears to the medical officer in charge that there is doubt about the physical or mental condition of an alien, completion of the examination shall be deferred for such observation and further examination of the alien as may be reasonably necessary to determine his physical or mental condition.

(b) When, in the judgment of the medical officer in charge, a medical examination in the United States or in a territory or possession thereof cannot be satisfactorily completed at a station or place at which it is undertaken, such examination shall be discontinued and such officer shall request of the Immigration Service that the alien be removed to a place where the examination may be satisfactorily completed.

§ 34.12 Applicability of Foreign Quarantine Regulations.

Aliens arriving at a port of the United States shall be subject to the applicable provisions of Part 71 of this chapter (Foreign Quarantine Regulations of the Public Health Service) with respect to examination and sanitary and quarantine measures.

§ 34.13 Medical and other care; death.

(a) Upon request by the Immigration Service, an alien detained by it shall be admitted to a hospital or station of the Public Health Service and receive therein necessary medical, surgical, and dental care. An alien found to be in need of emergency care in the course of an examination or reexamination in the United States, or in a territory or possession thereof, shall be given such care to the extent deemed practicable by the medical officer in charge, and if in need of further care he shall be referred to the immigration authority concerned, with the medical examiner's recommendations concerning such further care.

(b) In case of death of an alien the body shall be delivered to the consular or immigration authority concerned; but if such death occurs in the United States, or in a territory or possession thereof, public burial shall be provided upon request of the Immigration Service and subject to its agreement to pay the burial expenses. Autopsies shall not be performed unless approved by the Immigration Service.

§ 34.14 Reexamination; convening of boards; expert witnesses; reports.

(a) The Surgeon General or, when authorized, the medical officer in charge, shall convene a board of medical officers to reexamine an alien:

(1) Upon the request of the Immigration Service for a reexamination by such a board, or

(2) Upon an appeal by an alien who, having received a medical examination in connection with determination of admissibility to the United States (including examination on arrival and adjustment of status as provided in the immigration laws and regulations) has been certified for: Mental retardation; insanity; one or more previous attacks of insanity; psychopathic personality; sexual deviation; mental defect; narcotic drug addiction or chronic alcoholism.

(b) Such a board shall consist of three, when practicable, but in no case less than two, medical officers. If a board of two officers is unable to reach agreement, a new board shall be convened and shall reexamine the alien. In the event that a board consists of three medical officers, the decision of the majority thereof shall prevail.

(c) Reexamination shall include:

(1) A medical examination by the board. If the mental condition of the alien is in question and the board does not include at least one officer who has had special training in the diagnosis of mental defects, diseases, and disabilities, the board shall designate a physician with such training who shall also examine the alien, and his report shall be included in the record.

(2) A review of all records submitted by the alien, other witnesses, or the board.

(3) Use of any laboratory or diagnostic methods or tests deemed advisable.

(4) Consideration of statements regarding the alien's physical or mental condition made by a physician after his examination of the alien.

(d) An alien who is to be reexamined shall be notified of the time and place of his reexamination not less than five days prior thereto.

(e) The alien may introduce as witnesses before the board such physicians or medical experts as the board may in its discretion permit, at his own cost and expense: *Provided,* That the alien shall be permitted to introduce at least one expert medical witness. If any witnesses offered are not permitted by the board to testify, the record of the proceedings shall show the reason for the denial of permission.

(f) Witnesses before the board shall be given a reasonable opportunity to examine medical certificates and other records involved in the reexamination and to present all relevant and material evidence orally or in writing until such time as the proceedings are declared by the board to be closed. During the course of the hearing the alien's attorney or representative shall be permitted to examine the alien and he, or the alien, shall be permitted to examine any witnesses offered in the alien's behalf and to cross-examine any witnesses called by the board. If the alien does not have an attorney or representative, the board shall assist the alien in the presentation of his case to the end that all of the material and relevant facts may be adduced.

(g) The findings and conclusions of the board shall be based on its medical examination of the alien and on the evidence presented and made a part of the record of its proceedings.

(h) The board shall report its findings and conclusions to the Immigration Service, and shall also give prompt notice thereof to the alien if the reexamination has been held upon his appeal. The board's report to the Immigration Service shall specifically affirm, modify, or reject the findings and conclusions of prior examining medical officers.

(i) If the board finds that an alien reexamined by it has a defect, disease, or disability, or has had one or more attacks of insanity, not previously certified, it shall issue its certificate in accordance with the applicable provisions of this part.

(j) After submission of its report the board shall not be reconvened, nor shall a new board be convened, in connection with the same application for admission or for adjustment of status, except upon the express authorization of the Surgeon General.

[21 FR 9829, Dec. 12, 1956, as amended at 30 FR 16112, Dec. 28, 1965]

PART 35—HOSPITAL AND STATION MANAGEMENT

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AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216, sec. 321, 53 Stat. 695, as amended; 42 U.S.C. 248, unless otherwise noted.

SOURCE: 21 FR 9830, Dec. 12, 1956, unless otherwise noted.

Subpart A—General

§ 35.1 Hospital and station rules.

The officer in charge of a station or hospital of the Service is authorized to adopt such rules and issue such instructions, not inconsistent with the regulations in this part and other provisions of law, as he deems necessary for the efficient operation of the station or hospital and for the proper and humane care and treatment of all patients therein. All general rules governing the conduct and privileges of patients, and of members of the public while on the premises, shall be posted in prominent places.

§ 35.2 Compliance with hospital rules.

All patients and visitors in stations and hospitals of the Service are expected to comply with the rules and instructions issued under the authority of the officer in charge.

§ 35.3 Noncompliance; deprivation of privileges.

Any patient who wilfully fails or refuses to comply with rules or instructions of a hospital or station or with regulations of the Service, may, by the direction of the officer in charge, be deprived of recreational or other privileges accorded patients. Any visitor who wilfully fails or refuses to comply with any such rules, instructions, or regulations may, by direction of the officer in charge, be denied visiting privileges.

§ 35.4 Noncompliance; discharge or transfer.

(a) If the officer in charge finds, upon investigation, that a patient other than a leprosy patient, by willful and persistent failure or refusal to comply with such rules, instructions, or regulations is seriously impeding the course of his own care and treatment, or that of other patients, he may (1) discharge the patient, or (2) if the patient is not a voluntary patient, arrange for his transfer to the custody of the authority responsible for his admission to the station or hospital. No patient shall be discharged or transferred on account of noncompliance if to do so would seriously endanger his life or health, nor shall any patient be discharged if his failure to comply is due, in the opinion of the officer in charge, to a mental disease or disorder.

(b) If the discharge or transfer of a patient is likely to endanger the health of persons other than the patient or officers or employees of the station or hospital, the officer in charge shall give advance notice to appropriate State, county, or municipal authorities of the discharge or transfer.

§ 35.5 Entitlement to care after discharge or transfer by reason of noncompliance.

No person otherwise entitled to care, treatment, or hospitalization at Service facilities, or in other facilities at the expense of the Service, shall be denied such care or treatment by reason of his prior discharge or transfer from any such facility under the provisions of § 35.4.

§ 35.6 Admissions; determination of eligibility for care.

Except as may otherwise be provided for specific classes of patients by the regulations of this chapter, the officer in charge of the station or hospital to which application is made is authorized to determine the eligibility of applicants, as beneficiaries of the Service, for care and for treatment. Such determinations shall be subject to review by the chief of the division of the Service responsible for administration of the station or hospital concerned upon referral made by the officer in charge in doubtful cases or upon appeal made by an applicant who has been denied care or treatment.

§ 35.7 Admissions; designation of person to be notified.

Every in-patient, at the time of admission to the hospital or station or as soon thereafter as practicable, shall be requested to designate a person or persons to be notified in case of emergency.

§ 35.8 Safekeeping of money and effects; withdrawals.

(a) A place for the safekeeping of money and effects of patients shall be provided at each station or hospital, and an itemized receipt therefor shall be furnished to the patient and to any other person who places money or effects therein for the benefit of the patient.

(b) Money and effects may be withdrawn only by or on behalf of the patient, by his legally appointed representative authorized to receive or dispose of his property (including the money and effects in the custody of the station or hospital), or by a person who is authorized, under the law of the State in which the station or hospital is located, to receive or dispose of the patient's money and effects. In any case in which the officer in charge has had actual notice of the appointment of a legal representative, withdrawals may be made only by such representative or in accordance with his written directions. No delivery shall be made under this paragraph unless (1) the person receiving the money or effects shall sign an itemized receipt therefor, or (2) the delivery is witnessed by two persons. The provisions of this paragraph do not prohibit withdrawals made necessary by the provisions of this part for the disposition of money and effects left by patients on death or on departure from the station or hospital, or by the provisions of § 35.10.

§ 35.9 Disposition of money and effects left by other than deceased patients.

Money and effects left on the premises by a patient shall be forwarded promptly to him. If because his whereabouts are unknown his money and effects cannot be delivered to him within 120 days after his departure, his money shall be deposited into the Treasury and credited to the account entitled "Money and Effects of Former Patients (PHS (T) name of patient)," and his effects shall be held for him for six months and then sold in accordance with § 35.49, and the proceeds deposited into the Treasury and credited to the above account.

§ 35.10 Destruction of effects dangerous to health.

The officer in charge shall cause to be destroyed effects brought into or received in the station or hospital area by patients which, in the judgement of such officer, are dangerous as a source of disease to the health or life of patients or personnel of the station or hospital or visitors therein and cannot otherwise be safely disposed of or rendered harmless by disinfection or other means. The destruction of effects shall be witnessed by at least one officer or employee designated for that purpose by the officer in charge, and appropriate records of the destruction shall be maintained.

§ 35.11 Clinical records; confidential.

A complete clinical record shall be maintained for each patient admitted to a station or hospital of the Service. Such records shall be confidential and shall not be disclosed except as may be provided elsewhere in regulations of the Service.

§ 35.12 Solicitation of legal business prohibited.

The solicitation, directly or indirectly, of legal business or of a retainer or agreement authorizing an attorney to render legal services, is prohibited in all stations and hospitals of the Service.

§ 35.13 Entry for negotiation of release or settlement.

(a) No person shall be permitted to enter a station or hospital of the Service for the purpose of negotiating a settlement or obtaining a general or special release or statement from any patient with reference to any illness or personal injury for which the patient is receiving care or treatment, or for the purpose of conferring with him as an attorney or representative of an attorney with reference to such illness or injury, unless the patient has signified his willingness to have such person enter for such purpose and, in the judgment of the officer in charge, the physical or mental condition of the patient will not thereby be impaired.

(b) Any person entering a station or hospital for a purpose enumerated in paragraph (a) of this section shall register in the manner prescribed by the officer in charge, and shall furnish for the records of the station or hospital the name of each patient by whom he has been received for such a purpose.

§ 35.14 Solicitation of legal business; negotiation of release or settlement; assistance prohibited.

All employees of the Service and all persons attached in any capacity to a station or hospital, including patients, are forbidden to communicate, directly or indirectly, with any person for the purpose of aiding in the solicitation of legal business or in the negotiation of a settlement or the obtaining of a general or special release or statement from any patient with reference to any illness or personal injury for which the patient is receiving care or treatment therein. No patient is prohibited by this section from communicating on his own behalf with an attorney of his choice or with other persons.

§ 35.15 Consent to operative procedures.

Except in emergencies when the patient is physically or mentally incapable of consenting and the delay required to obtain the consent of his natural or legal guardian would seriously endanger the patient's health, no operative procedure shall be undertaken unless the patient or, in the case of a minor or incompetent, his natural or legal guardian gives his consent, nor shall any major operative procedure or the administration of a general anaesthetic be undertaken unless such consent has been obtained in writing. The consent or refusal of consent shall be made a part of the clinical record.

§ 35.16 Autopsies and other post-mortem operations.

Autopsies, or other post-mortem operations, including removal of tissue for transplanting, may be performed on the body of a deceased patient only by direction of the officer in charge and only if consented to in writing by a person authorized under the law of the State in which the station or hospital is located to permit an autopsy or such other post-mortem operation under the circumstances of the particular death involved. Restrictions or limitations imposed by the person consenting thereto on the extent of the autopsy or other post-mortem operation shall be observed. Documents embodying consent shall be made a part of the clinical record.

[25 FR 6331, July 6, 1960]

§ 35.17 Fees and charges for copying, certification, search of records and related services.

A prescribed fee, in accordance with the schedule in paragraph (c) of this section, shall be collected for each of the listed services.

(a) *Application for services.* Any person requesting (1) a copy of a clinical record, clinical abstract, or other document containing clinical information; or (2) a certification of a clinical record or document; or (3) a search of clinical records, shall make written application therefor to the Public Health Service facility having custody of the subject matter involved. Such application shall state specifically the particular record or document requested, and the purpose for which such copy or document is desired to be used. The application shall be accompanied by a deposit in an amount equal to the prescribed charge for the service rendered. Where it is not known if a clinical record or other document is in existence, the application shall be accompanied by a minimum deposit of $2.50.

(b) *Authorization for disclosure.* The furnishing of copies of PHS records containing confidential clinical information must comply with the requirements of Part I, Title 42, Code of Federal Regulations, governing authorization for the disclosure of such information.

(c) *Schedule of fees.*

(1) Photocopy reproduction of a clinical record or other document (through use of facility equipment):	
(a) Processing (searching, preparation of record and use of equipment), first page	$3.25
(b) Each additional page	.25

(2) Certification, per document	.25
(3) Unsuccessful searching, per hour (minimum charge 1 hour)	2.50
(4) Clinical abstracts, per request	3.00
(5) Arranging commercial duplication of a clinical record, per request	[1]0.50
(6) If the requested material is to be transmitted by registered mail, airmail, or special delivery mail, the postal fees therefor shall be added to the other fees provided above, unless the applicant has included proper postage or stamped return envelopes for this purpose.	

[1] The private concern which duplicates records for an applicant will make a separate charge therefor and will bill the applicant directly.

(d) *Waiver of fee.* The prescribed fee may be waived, in the discretion of the medical officer in charge, under the following circumstances:

(1) When the service or document is requested by another agency of the Federal Government for use in carrying out official Government business.

(2) When a clinical record is requested for the purpose of providing continued medical care to a Service beneficiary by a non-Service physician, clinic, or hospital, in which case the record will be forwarded only to the physician, clinic, or hospital concerned.

(3) When the service or document is requested by an attorney in the prosecution of a Service beneficiary's personal injury claim against a third person, involving the concurrent assertion of a government medical care claim under 42 U.S.C. 2651-2653. In such case, the service or document requested will be furnished only upon compliance with all additional requirements for the release of records in third party recovery cases, including the proper execution of form PHS-4686, Agreement to Assign Claim Upon Request.

(4) When the service or document is requested by, and furnished to, a Member of Congress for official use.

(5) When the service or document is requested by, and furnished to, a court in lieu of the personal court appearance of an employee of the Public Health Service.

(6) When the service or document is required to be furnished free in accordance with a Federal statute or an Executive order.

(7) When the furnishing of the service or document requested without charge would be an appropriate courtesy to a foreign country or international organization.

(Sec. 501, 65 Stat. 290; 31 U.S.C. 483(a); sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216)

[32 FR 6842, May 4, 1967]

Subpart B—Transfer of Patients

§ 35.21 Authorization of transfer.

Except as otherwise provided by law or regulation with respect to certain classes of patients, the officer in charge of a station or hospital of the Service may provide, without any cost to the patient, for the transfer of the patient either from such station or hospital to another station or hospital of the Service or to any non-Service station or hospital at which the patient may be received, or from any non-Service hospital at which he is receiving care or treatment as a patient of the Service to a station or hospital of the Service.

§ 35.22 Attendants.

Patients shall be transferred by such means and accompanied by such medical, nursing, or other attendants as may be necessary to protect the health and safety of the patient and other persons likely to come into contact with him, including in the case of a prisoner such guards as may be necessary to assure his safekeeping. A female patient requiring the services of attendants shall be accompanied by at least one female attendant. Medical or nursing attendants shall be qualified to care for persons suffering from the type of disease or disorder with which the patient is afflicted and shall be provided with equipment and medicines necessary for the care of the patient.

Subpart C—Disposition of Articles Produced by Patients

§ 35.31 Retention by patients.

Subject to the rules of the station or hospital, patients may be accorded the privilege of retaining articles produced by them in the course of their curative treatment with the aid of materials furnished by the Service. Articles not retained by patients shall be disposed

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of as provided in this subpart. The provisions of this subpart do not apply to the products of industrial activities established for narcotic addicts.

§ 35.32 Board of appraisers.

The officer in charge shall appoint, from the personnel of the station or hospital, a board of three persons to serve at his pleasure. The board shall provide for the sale of articles having commercial value and shall keep appropriate records of such articles and their disposition.

§ 35.33 Sale; prices; deposit of proceeds.

The board shall determine and redetermine from time to time the prices at which articles are to be sold, and in doing so shall consider the cost of materials used, reasonable handling charges, and the fair market value of the articles. The sale price shall be indicated on each article by tag or other appropriate means, and a list of articles offered for sale and their respective sale prices shall be posted from time to time in the hospital or station area. In its discretion, the board may offer such articles for purchase by other patients or by charitable organizations before offering them for purchase to the general public. No article shall be sold or resold to any officer or employee of the Service. Moneys received from the sale of articles shall be deposited into the Treasury to the credit of the appropriation from which the materials for making such articles were purchased.

§ 35.34 Resale.

No article purchased under the provisions of this subpart shall be resold in the hospital or station area at a price to exceed the sale price fixed by the board for such article.

§ 35.35 Unsalable articles.

Articles having no commercial value shall be stored, destroyed, or otherwise disposed of as the officer in charge may direct.

Subpart D—Disposal of Money and Effects of Deceased Patients

§ 35.41 Inventory.

Promptly after the death of a patient in a station or hospital of the Service, an inventory of his money and effects left therein shall be made by two or more officers or employees of the Service designated for such purpose by the officer in charge.

§ 35.42 Notice upon death.

The officer in charge shall notify in writing all persons known to him to whom delivery of the patient's money and effects might be made hereunder, and, in the case of an alien patient, a consul of the country of his apparent nationality. Each person so notified shall be requested to furnish information concerning (a) the existence or whereabouts of any persons to whom delivery of the deceased patient's money and effects may be made pursuant to these provisions, and (b) the permanent residence or home of the deceased.

§ 35.43 Delivery only upon filing claim; forms; procedure.

(a) Delivery of the money and effects of a deceased patient shall be made only to a person who has filed a claim therefor on a form prescribed by the Surgeon General.

(b) A claimant shall furnish, in addition to the information on the prescribed form, such additional information as the officer in charge may consider necessary to establish the identity of the claimant and the truth of his statements.

(c) A person filing a claim as a legal representative shall be required to present letters of administration or a certificate of a court attesting his qualification or appointment.

(d) If a claim is made after the money, or proceeds from the sale of the effects, of a deceased patient have been deposited in the Treasury, the claim shall be referred to the General Accounting Office. If the claim is for checks or evidences of indebtedness of the United States which have been trasnsmitted to the issuing agency pursuant to §§ 35.47 and 35.48, the claimant shall be referred to such agency.

§ 35.44 Delivery to legal representative; to other claimants if value is $1,000 or less.

The money and effects of the deceased patient shall in all cases be delivered to the legal representative, if any, of his estate. If the value is $1,000 or less, and the officer in charge has neither notice nor other knowledge of the appointment or qualification of a legal representative, nor reason to believe that a legal representative will be appointed or qualified, he shall deliver all the money and effects, as soon as practicable after the expiration of 10 days from the sending of notices to one of the following in the indicated order of priority:

(a) A person, if any, designated in writing by the patient to receive the same.

(b) The patient's surviving spouse.

(c) The patient's child or children in equal parts.

(d) The patient's parent or parents in equal parts.

(e) Any other person who would be entitled to receive the money and effects under the law of the patient's domicile: *Provided*, That delivery of such money and effects may be made immediately upon application by one of the persons specified above if the officer in charge has neither notice nor other knowledge that a person higher in the indicated order of priority exists.

§ 35.45 Disposition of effects; exceptions.

Irrespective of the provisions of this subpart, the officer in charge may (a) release from among the effects of the deceased patient so much of the patient's clothing as may be necessary for use in preparation of his body for burial and (b) cause to be destroyed, or otherwise disposed of, such used toilet articles of the patient as appear to have no commercial or other value.

§ 35.46 Conflicting claims.

In any case in which conflicting claims are filed or the officer in charge considers it to be in the interest of persons who may be ultimately entitled thereto, delivery may be withheld from all persons other than a duly qualified legal representative.

§ 35.47 Disposition of Government checks.

Notwithstanding any other provisions of this subpart, immediately upon completion of the inventory, checks drawn on the Treasurer of the United States shall be sent by safe means to the department, agency, or establishment of the Government of the United States issuing such checks. The transmittal shall be accompanied by a statement of the reasons therefor and of all available information which may aid the issuing unit in the disposition of the check transmitted. Notice of the disposition of any checks, with identifying information, shall be given to the person or persons, if any, to which money and effects are delivered in accordance with § 35.44.

§ 35.48 Deposit of unclaimed money; sale of unclaimed effects and deposit of proceeds.

If, within 120 days after sending of notices no claim has been filed pursuant to the provisions of § 35.43, the patient's money, consisting of all types of United States currency and coin, shall be deposited in the Treasury to the credit of the trust-fund account entitled "Money and Effects of Deceased Patients, Public Health Service." If, within six months after the death of a patient, no claim has been filed pursuant to the provisions of § 35.43, his effects (including foreign currency and coin but excluding Postal Savings Certificates and other evidences of indebtedness of the United States) shall be sold at public auction or by sealed bids to the highest bidder and the proceeds deposited to the credit of the trust-fund account entitled "Money and Effects of Deceased Patients, Public Health Service." Postal Savings Certificates and other evidences of indebtedness of the United States shall be transmitted to the issuing department or agency with a statement of the occasion therefor.

§ 35.49 Sale of unclaimed effects; procedures.

The following provisions shall govern the sale of effects:

(a) *Notice.* Reasonable advance notice of proposed sales shall be posted at such prominent places in the station or hospital area as the officer in charge may designate. In addition, a notice shall be posted at the nearest post office, and notices shall be sent by mail to all known persons to whom delivery of money and effects of the patient may be made under the provisions of this subpart. The officer or employee who posts or sends notices of sales shall make an appropriate affidavit on a copy of the notice as to his action in that respect, including in his affidavit the names of persons to whom copies of the notices were mailed and the mailing dates. The copy of the notice on which the affidavit appears shall be retained in the files of the station or hospital.

(b) *Form and contents of notice.* Notice of proposed sales shall be given on a form prescribed by the Surgeon General. The notice shall include: an inventory of the effects to be offered for sale; the names of the patients from whom the effects were received; the precise date, time, and place when and where the sale will be held; a statement that the articles will be available for inspection immediately prior to sale, if sold at public auction, or on a day and during the hours appointed for the inspection of articles if sold by sealed bid; a statement that the sale is to be held pursuant to the provisions of the regulations in this part, that, if the articles are to be sold by sealed bid, the right to reject all bids is reserved, and that, if otherwise authorized, delivery will be made of effects or proceeds of sales to persons filing claims prior to the sale of effects or prior to the transmittal of proceeds to the Surgeon General.

(c) *Time and place of sales.* All sales shall be held at reasonable hours and at such places within the station or hospital area as the officer in charge may designate.

(d) *Who shall conduct sales.* All sales shall be conducted by the officer in charge or by a responsible officer or employee designated by him.

(e) *Sale and delivery.* All effects offered for sale shall be sold to the highest bidder and delivered to him immediately upon payment of the sale price in cash or by postal money order or certified check and execution of an appropriate receipt by the person to whom delivery is made.

§ 35.50 Disposition of unsold effects.

The officer in charge shall dispose of effects offered for sale but remaining unsold in such manner as he considers to be proper, but, if practicable, such effects shall be used for the benefit of other patients of the Service.

§ 35.51 Manner of delivery; costs, receipts.

(a) If a person entitled under this subpart to receive the money and effects of a patient is unable to take possession thereof at the station or hospital, they shall be sent to him at the expense of the United States in the most economical manner available. The records of the station or hospital shall show the names and addresses of persons to whom money or effects have been sent, the date of sending, the means used, an itemized list of the money or effects sent, and a statement by a witnessing officer or employee verifying the foregoing from his own observation.

(b) If not delivered personally by an authorized officer or employee of the Service, money, evidences of indebtedness, and other valuable papers and documents shall be sent by registered mail (or other safe means).

(c) Persons receiving the money and effects of a patient shall be required to execute an itemized receipt therefor.

§ 35.52 Delivery of possession only; title unaffected.

Except for delivery of effects to purchasers at sales held in accordance with § 35.49, delivery or deposit under this subpart of the money or effects, or the proceeds of a sale of the effects, of a deceased patient constitutes only a transfer of possession and is not intended to affect in any manner the title to such money, effects, or proceeds.

Subpart E—Contributions for the Benefit of Patients

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 63 Stat. 835 (42 U.S.C. 216); sec. 321, 58 Stat. 695, as amended, 62 Stat. 1017 (42 U.S.C. 248).

SOURCE: 42 FR 60742, Nov. 29, 1977, unless otherwise noted.

§ 35.61 Applicability.

This subpart sets forth the policies and procedures governing the acceptance and administration of contributions of money or property intended solely for the benefit of all patients in a ward or unit or a particular hospital or station of the Public Health Service, excluding outpatient clinics. Such contributions are distinguishable from (a) monies or other valuables belonging to specific patients which are accepted and held in custody for the convenience of the patient until such time as he or she wishes to withdraw them, and (b) gifts to the United States to support Public Health Service functions under section 501 of the Public Health Service Act or other statutory provisions, which may be accepted and administered only in accordance with such statutory provisions or other applicable laws.

§ 35.62 Acceptance of contributions.

(a) The officer in charge of a hospital or station or his delegate may accept contributions of money or personal property which are donated for the general benefit of all patients within the hospital or station (or a ward or unit thereof) without further specification or conditions as to use. Contributions tendered subject to conditions by the donor, such as expenditure or use only on behalf of certain patients or for specific purposes, may not be accepted.

(b) Contribution of money or property shall be accepted in writing.

§ 35.63 Report of and accounting for contributions.

(a) Contributions of money accepted pursuant to § 35.62 (hereinafter referred to as "patient fund") will be treated consistently with Federal deposit rules and as supplemented with appropriate procedures of the facility. This regulation is not intended to exclude contributions for the benefit of patients from proper accountability and control of funds and property.

(b) Contributions of property accepted pursuant to § 35.62 shall be recorded and accounted for in the same manner as other property of a similar kind maintained in the hospital or station, but with suitable identification so that it can be distinguished from government-owned property.

§ 35.64 Donors.

Authorized contributions may be accepted from patients, employees and other individuals, and agencies and organizations.

§ 35.65 Acceptable personal property.

Contributions of personal property which may be accepted pursuant to § 35.62 include, but are not limited to, recreational equipment, furniture, radios and television sets. After its useful life, any cash proceeds realized upon disposition of such property shall be deposited to the credit of the patient fund and shall be available for expenditure pursuant to § 35.66(c).

§ 35.66 Expenditure of cash contributions.

(a) Officials authorized to accept contributions shall not maintain control over the actual obligation or expenditure of such monies.

(b) Only those officers or employees specifically designated in writing by the officer in charge for such purpose may obligate and expend monies from the patient fund. The names of officials so designated shall be provided to the relevant fiscal control office.

(c) Subject to availability of sufficient funds, monies in the patient fund may be expended for materials, services or activities which contribute to the well-being or morale of patients, including but not limited to provision of reading and entertainment materials, recreation activities, and, in appropriate cases, necessary financial support (including travel expenses, meals, and lodging) of relatives, guardians, or friends of patients to enable such persons to be available for the patient's comfort and support.

(d) Officers in charge may issue such additional instructions, not inconsistent with this subpart, as may be necessary to implement its provisions.

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AUTHORITY: Sec. 3, 68 Stat. 674; 42 U.S.C. 2003, 42 Stat. 208, sec. 1, 68 Stat. 674; 25 U.S.C. 13, 42 U.S.C. 2001, unless otherwise noted.

Subpart A—Purpose and Definitions

SOURCE: 46 FR 40692, Aug. 11, 1981, unless otherwise noted.

§ 36.1 Definitions.

When used in this part:

"Bureau of Indian Affairs" means the Bureau of Indian Affairs, Department of the Interior;

"Indian" includes Indians in the Continental United States, and Indians, Aleuts and Eskimos in Alaska;

"Indian health program" means the health services program for Indians administered by the Indian Health Service within the Department of Health and Human Services.

"Jurisdiction" has the same geographical meaning as in Bureau of Indian Affairs usage;

"Service" means the Indian Health Service.

§ 36.2 Purpose of the regulations.

These regulations establish general principles and program requirements for carrying out the Indian health program.

§ 36.3 Administrative instructions.

The Service periodically issues administrative instructions to its officers and employees which are primarily

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found in the Indian Health Service Manual and the Area Office and Program Office supplements. These instructions are operating procedures to assist officers and employees in carrying out their responsibilities, and are not regulations establishing program requirements which are binding upon members of the general public.

Subpart B—What Services are Available and Who is Eligible to Receive Care?

Source: 46 FR 40692, Aug. 11, 1981, unless otherwise noted.

§ 36.11 Services available.

(a) Type of services that may be available. Services for the Indian community served by the local facilities and program may include hospital and medical care, dental care, public health nursing and preventive care including immunizations, and health examination of special groups such as school children.

(b) Where services are available. Available services will be provided at hospitals and clinics of the Service, and at contract facilities (including tribal facilities under contract with the Service).

(c) Determination of what services are available. The Service does not provide the same health services in each area served. The services provided to any particular Indian community will depend upon the facilities and services available from sources other than the Service and the financial and personnel resources made available to the Service.

§ 36.12 Persons to whom services will be provided.

(a) *In general.* (1) Services will be made available, as medically indicated, to persons of Indian descent belonging to the Indian community served by the local facilities and program, and non-Indian wives of such persons.

(2) Generally, an individual may be regarded as within the scope of the Indian health and medical service program if he is regarded as an Indian by the community in which he lives as evidenced by such factors as tribal membership, enrollment, residence on tax-exempt land, ownership of restricted property, active participation in tribal affairs, or other relevant factors in keeping with general Bureau of Indian Affairs practices in the jurisdiction.

(b) *Doubtful cases.* (1) In case of doubt as to whether an individual applying for care is within the scope of the program, the Medical Officer in Charge shall obtain from the appropriate Bureau of Indian Affairs officials in the jurisdiction information pertinent to his determination of the individual's continuing relationship to the Indian population group served by the local program.

(2) If the applicant's condition is such that immediate care and treatment are necessary, services shall be provided pending identification as an Indian beneficiary.

(c) *Priorities when funds, facilities, or personnel are insufficient to provide the indicated volume of services.* Priorities for care and treatment, as among individuals who are within the scope of the program, will be determined on the basis of relative medical need and access to other arrangements for obtaining the necessary care.

[21 FR 9833, Dec. 12, 1956]

§ 36.13 [Reserved]

§ 36.14 Care and treatment of ineligible individuals.

(a) In case of emergency, as an act of humanity, individuals not eligible under §36.12 may be provided temporary care and treatment in Service facilities.

(b) Charging ineligible individuals. Where the Service Unit Director determines that an ineligible individual is able to defray the cost of care and treatment, the individual shall be charged at rates approved by the Assistant Secretary for Health and Surgeon General published in the Federal Register. Reimbursement from third party payors may be arranged by the patient or by the Service on behalf of the patient.

Subpart C—Contract Health Services

SOURCE: 43 FR 34654, Aug. 4, 1978, unless otherwise noted.

§ 36.21 Definitions.

As used in this subpart:

(a) "Alternate resources" means resources other than those of the Indian Health Service contract health services program, available and accessible to the individual, such as health care providers and institutions (including facilities operated by the Indian Health Service), health care payment sources, or other health care programs for the provision of health services (e.g., medicare or medicaid) for which the individual may be eligible.

(b) "Appropriate ordering official" means, unless otherwise specified by contract with the health care facility or provider, the ordering official for the contract health service delivery area in which the individual requesting contract health services or on whose behalf the services are requested, resides.

(c) "Area Director" means the Director of an Indian Health Service area designated for purposes of administration of Indian Health Service programs.

(d) "Contract health service delivery area" means the geographic area within which contract health services will be made available by the IHS to members of an identified Indian community who reside in the area, subject to the provisions of this subpart.

(e) "Contract health services" means health services provided at the expense of the Indian Health Service from public or private medical or hospital facilities other than those of the Service.

(f) "Emergency" means any medical condition for which immediate medical attention is necessary to prevent the death or serious impairment of the health of an individual.

(g) "Indian tribe" means any Indian tribe, band, nation, group, Pueblo, or community, including any Alaska Native village or Native group, which is federally recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(h) "Program Director" means the Director of an Indian Health Service "program area" designated for the purposes of administration of Indian Health Service programs.

(i) "Reservation" means any federally recognized Indian tribe's reservation, Pueblo, or colony, including former reservations in Oklahoma, Alaska Native regions established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 et seq.), and Indian allotments.

(j) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(k) "Service" means the Indian Health Service.

(l) "Service Unit Director" means the Director of an Indian Health Service "Service unit area" designated for purposes of administration of Indian Health Service programs.

§ 36.22 Establishment of contract health service delivery areas.

(a) In accord with the congressional intention that funds appropriated for the general support of the health program of the Indian Health Service be used to provide health services for Indians who live on or near Indian reservations, contract health service delivery areas are established as set out below:

(1) The State of Alaska;

(2) The State of Nevada;

(3) The State of Oklahoma,

(4) Chippewa, Mackinac, Luce, Alger, Schoolcraft, Delta, and Marquette Counties in the State of Michigan;

(5) Clark, Eau Claire, Jackson, LaCrosse, Monroe, Vernon, Crawford, Shawano, Marathon, Wood, Juneau, Adams, Columbia, and Sauk Counties in the State of Wisconsin and Houston County in the State of Minnesota.

(6) With respect to all other reservations within the funded scope of the Indian health program, the contract health services delivery area shall consist of a county which includes all or part of a reservation, and any county

or counties which have a common boundary with the reservation.

(b) The Secretary may, from time to time, redesignate areas or communities within the United States as appropriate for inclusion or exclusion from a contract health service delivery area after consultation with the tribal governing body or bodies of those reservations included within the contract health service delivery area. The Secretary will take the following criteria into consideration:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of contract health services.

(c) Any redesignation under paragraph (b) of this section shall be made in accordance with the procedures of the Administrative Procedure Act (5 U.S.C. 553).

§ 36.23 Persons to whom contract health services will be provided.

(a) *In general.* To the extent that resources permit, and subject to the provisions of this subpart, contract health services will be made available as medically indicated, when necessary health services by an Indian Health Service facility are not reasonably accessible or available, to persons described in and in accordance with § 36.12 of this part if those persons:

(1) Reside within the United States and on a reservation located within a contract health service delivery area; or

(2) Do not reside on a reservation but reside within a contract health service delivery area, and: (i) Are members of the tribe or tribes located on that reservation or of the tribe or tribes for which the reservation was established, or (ii) maintain close economic and social ties with that tribe or tribes.

(b) *Students and transients.* Subject to the provisions of this subpart, contract health services will be made available to students and transients who would be eligible for contract health services at the place of their permanent residence within a contract health service delivery area, but are temporarily absent from their residence, as follows:

(1) Students—during their full-time attendance at programs of vocational, technical, or academic education, including normal school breaks, such as vacations, semester or other scheduled breaks occurring during their attendance, and for a period not to exceed 180 days after the completion of the course of study.

(2) Transients (persons who are in travel or are temporarily employed, such as seasonal or migratory workers), during their absence.

(c) *Other persons outside the contract health service delivery area.* Persons who leave the contract health service delivery area in which they are eligible for contract health services and are neither students or transients will be eligible for contract health services for a period not to exceed 180 days from such departure.

(d) *Foster children.* Indian children who are placed in foster care outside a contract health service delivery area by order of a court of competent jurisdiction and who were eligible for contract health services at the time of the court order shall continue to be eligible for contract health services while in foster care.

(e) *Priorities for contract health services.* When funds are insufficient to provide the volume of contract health services indicated as needed by the population residing in a contract health service delivery area, priorities for service shall be determined on the basis of relative medical need.

(f) *Alternate resources.* Contract health services will not be authorized by the Indian Health Service when, and to the extent that, alternate resources for the provision of necessary medical services are available and accessible to the individual requesting the services or would be available and accessible upon application of the individual to the alternate resource.

[43 FR 34654, Aug. 4, 1978; 43 FR 41214, Sept. 15, 1978]

§ 36.24 Authorization for contract health services.

(a) No payment will be made for medical care and services obtained from non-Service providers or in non-Service facilities unless the applicable requirements of paragraphs (b) and (c) below have been met and a purchase order for the care and services has been issued by the appropriate ordering official to the medical care provider.

(b) In nonemergency cases, a sick or disabled Indian, or an individual or agency acting on behalf of the Indian, or the medical care provider shall, prior to the provision of medical care and services, notify the appropriate ordering official of the need for services and supply information that the ordering official deems necessary to determine the relative medical need for the services and the individual's eligibility. The requirement for notice prior to providing medical care and services under this paragraph may be waived by the ordering official if:

(1) Such notice and information is provided within 72 hours after the beginning of treatment or admission to a health care facility; and

(2) The ordering official determines that giving of notice prior to obtaining the medical care and services was impracticable or that other good cause exists for the failure to provide prior notice.

(c) In emergency cases, a sick or disabled Indian, or an individual or agency acting on behalf of the Indian, or the medical care provider shall, within 72 hours after the beginning of treatment for the condition or after admission to a health care facility notify the appropriate ordering official of the fact of the admission or treatment, together with information necessary to determine the relative medical need for the services and the eligibility of the Indian for the services. The 72-hour period may be extended if the ordering official determines that notification within the prescribed period was impracticable or that other good cause exists for the failure to comply.

§ 36.25 Reconsideration and appeals.

(a) Any person to whom contract health services are denied shall be notified of the denial in writing together with a statement of the reason for the denial. The notice shall advise the applicant for contract health services that within 30 days from the receipt of the notice the applicant:

(1) May obtain a reconsideration by the appropriate Service unit director of the original denial if the applicant submits additional supporting information not previously submitted, or

(2) If no additional information is submitted, may appeal the original denial by the Service unit director to the appropriate area or program director. A request for reconsideration or appeal shall be in writing and shall set forth the grounds supporting the request or appeal.

(b) If the original decision is affirmed on reconsideration, the applicant shall be so notified in writing and advised that an appeal may be taken to the area or program director within 30 days of receipt of the notice of the reconsidered decision. The appeal shall be in writing and shall set forth the grounds supporting the appeal.

(c) If the original or reconsidered decision is affirmed on appeal by the area or program director, the applicant shall be so notified in writing and advised that a further appeal may be taken to the Director, Indian Health Service, within 30 days of receipt of the notice. The appeal shall be in writing and shall set forth the grounds supporting the appeal. The decision of the Director, Indian Health Service, shall constitute final administrative action.

Subpart D—[Reserved]

Subpart E—Preference in Employment

AUTHORITY: 25 U.S.C. 44, 45, 46 and 472; Pub. L. 83-568, 42 U.S.C. 2003.

SOURCE: 43 FR 29783, July 11, 1978, unless otherwise noted.

§ 36.41 Definitions.

For purposes of making appointments to vacancies in all positions in the Indian Health Service a preference will be extended to persons of Indian descent who are:

(a) Members of any recognized Indian tribe now under Federal jurisdiction;

(b) Descendants of such members who were, on June 1, 1934, residing within the present boundaries of any Indian reservation;

(c) All others of one-half or more Indian blood of tribes indigenous to the United States;

(d) Eskimos and other aboriginal people of Alaska; or

(e) For three (3) years or until the Osage Tribe has formally organized, whichever comes first, effective July 17, 1981, a person of at least one-quarter degree Indian ancestry of the Osage Tribe of Indians, whose rolls were closed by an act of Congress.

(25 U.S.C. 472)

[43 FR 29783, July 11, 1978, as amended at 46 FR 54743, Nov. 4, 1981]

§ 36.42 Appointment actions.

(a) Preference will be afforded a person meeting any one of the definitions of § 36.41 whether the placement in the position involves initial appointment, reappointment, reinstatement, transfer, reassignment, promotion, or any other personnel action intended to fill a vacancy.

(b) Preference eligibles may be given a schedule A excepted appointment under 5 CFR 213.3116(b)(8). If the individuals are within reach on a Civil Service Register, they may be given a competitive appointment.

§ 36.43 Application procedure for preference eligibility.

To be considered a preference eligible, the person must submit with the employment application a Bureau of Indian Affairs certification that the person is an Indian as defined by § 36.41 except that an employee of the Indian Health Service who has a certificate of preference eligibility on file in the Official Personnel Folder is not required to resubmit such proof but may instead include a statement on the application that proof of eligibility is on file in the Official Personnel Folder.

Subpart F—Abortions and Related Medical Services in Indian Health Service Facilities and Indian Health Service Programs

AUTHORITY: Sec. 1, 42 Stat. 208, 25 U.S.C. 13; sec. 1, 68 Stat. 674, 42 U.S.C. 2001; sec. 3, 68 Stat. 674, 42 U.S.C. 2003.

SOURCE: 47 FR 4018, Jan. 27, 1982, unless otherwise noted.

§ 36.51 Applicability.

This subpart is applicable to the use of Federal funds in providing health services to Indians in accordance with the provisions of Subparts A, B, C, H, I and J of this part.

§ 36.52 Definitions.

As used in this subpart:

"Physician" means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery at an Indian Health Service or tribally run facility, or by the State in which he or she practices.

§ 36.53 General rule.

Federal funds may not be used to pay for or otherwise provide for abortions in the programs described in § 36.51, except under the Circumstances discribed in § 36.54.

§ 36.54 Life of the mother would be endangered.

Federal funds are available for an abortion when a physician has found and so certified in writing to the appropriate tribal or other contracting organization, or service unit or area director, that "on the basis of my professional judgement the life of the mother would be endangered if the fetus were carried to term." The certification must contain the name and address of the patient.

§ 36.55 Drugs and devices and termination of ectopic pregnancies.

Federal funds are available for drugs or devices to prevent implantation of the fertilized ovum, and for medical procedures necessary for the termination of an ectopic pregnancy.

§ 36.56 Recordkeeping requirements.

Documents required by § 36.54 must be maintained for three years pursuant to the retention and custodial requirements for records at 45 CFR 74.20 et seq.

§ 36.57 Confidentiality.

Information which is acquired in connection with the requirements of this subpart may not be disclosed in a form which permits the identification of an individual without the individual's consent, except as may be necessary for the health of the individual or as may be necessary for the Secretary to monitor Indian Health Service program activities. In any event, any disclosure shall be subject to appropriate safeguards which will minimize the likelihood of disclosures of personal information in identifiable form.

Subpart G—[Reserved]

Subpart H—Grants for Development, Construction, and Operations of Facilities and Services

AUTHORITY: Secs. 104, 107, 25 U.S.C. 450h(b), 450k; Sec. 3, Pub. L. 83-568, 42 U.S.C. 2003.

SOURCE: 40 FR 53143, Nov. 14, 1975, unless otherwise noted.

§ 36.101 Applicability.

The regulations of this subpart are applicable to grants awarded pursuant to section 104(b) of Pub. L. 93-638, 25 U.S.C. 450h(b) for (a) projects for development including feasibility studies, construction, operation, provision, or maintenance of services and facilities provided to Indians and, (b) for projects for planning, training, evaluation or other activities designed to improve the capacity of a tribal organization to enter into a contract or contracts pursuant to section 103 of the Act. Such grants may include the cost of training personnel to perform grant related activities.

§ 36.102 Definitions.

As used in this subpart:

(a) "Act" means Title I of the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638 (88 Stat. 2203).

(b) "Indian" means a person who is a member of an Indian tribe.

(c) "Indian tribe" means any Indian tribe, band, nation, rancheria, Pueblo, colony or community, including any Alaska Native Village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act, Pub. L. 92-203 (85 Stat. 688 which is recognized as eligible by the United States Government for the special programs and services provided by the United States to Indians because of their status as Indians.

(d) "Tribal organization" means:

(1) The recognized governing body of any Indian tribe; or

(2) Any legally established organization of Indians which is:

(i) Controlled, sanctioned or chartered by such governing body or bodies; or

(ii) Democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities.

(e) "Secretary" means the Secretary of the Department of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(f) "Grantee" means the tribe or tribal organization that receives a grant under section 104(b) of the Act and this subpart and assumes the legal and financial responsibility for the funds awarded and for the performance of the grant supported activity in accordance with the Act and these regulations.

(g) "Indian owned economic enterprise" means any commercial, industrial, or business activity established or organized for the purpose of profit which is not less than 51 percent Indian owned.

§ 36.103 Eligibility.

Any Indian tribe or tribal organization is eligible to apply for a grant under this subpart.

§ 36.104 Application.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such manner as the Secretary may prescribe.

(b) The application shall be executed by an individual or individuals authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the Act, the regulations of this subpart and the terms and conditions of any grant award.

(c) In addition to such other pertinent information as the Secretary may require, the application for a grant under this subpart shall contain the following:

(1) A description of the applicant including an indication whether the applicant is a Tribe or tribal organization, and if the latter:

(i) The legal and organizational relationship of the applicant to the Indians in the Area to be served or effected by the project.

(ii) A description of the current and proposed participation of Indians in the activities of applicant.

(iii) Whether applicant is controlled, sanctioned or chartered by the governing body of the Indians to be served, and if so, evidence of such fact.

(iv) If elected, a description of the election process, voting criteria, and extent of voter participation in the election designating the organization.

(2) A narrative description of the project including its goals and objectives and the manner in which the proposed project is compatible with published Indian Health Service statements of availability of funds, the manner in which those goals and objectives are to be attained, and a work and time schedule which will be utilized to accomplish each goal and objective.

(3) A description of applicant's staff, present or proposed, including their qualifications, academic training, responsibilities and functions.

(4) A description of the manner in which the staff is or will be organized and supervised to carry out proposed activities.

(5) A description of training to be provided as part of the proposed project.

(6) A description of the administrative, managerial, and organizational arrangements and resources to be utilized to conduct the proposed project.

(7) A budget for the entire period of the project for which support is sought.

(8) The intended financial participation, if any, of the applicant, specifying the type of contributions such as cash or services, loans of full or part-time staff, equipment, space materials or facilities, or other contributions.

(9) Where health services are to be provided, a description of the nature of the services to be provided and the population to be served.

(10) A description of the Federal property, real and personal, equipment, facilities and personnel which applicant proposes to utilize and a description of the arrangements which applicant has made or will make to assume responsibility for the operation and management of those facilities.

(d) The application shall contain assurances satisfactory to the Secretary that the applicant will:

(1) Obtain adequate liability insurance coverage or an explanation of why such insurance cannot or should not be obtained. Such insurance shall provide that prior to cancellation the Secretary must be notified and must further provide that each such policy of insurance carrier shall waive any right it may have to raise as a defense the tribe's sovereign immunity from suit but such waiver shall extend only to claims the amount and nature of which are within the coverage and limits of the policy and shall not authorized or empower such insurance carrier to waive or otherwise limit the tribe's sovereign immunity outside or beyond the coverage and limits of the policy of insurance.

(2) Where applicant is providing services, provide such services at a level and range which is not less than that provided by the Indian Health Service or that identified by the Service after negotiation with the applicant, as an appropriate level, range and standard of care.

(3) Where providing services, provide services in accordance with law and applicable Indian Health Service policies and regulations.

(4) Where providing services, provide services in a fair and uniform manner, consistent with medical need, to all Indian people.

§ 36.105 Project elements.

A project supported under this subpart must:

(a) Have sufficient, adequately trained staff in relation to the scope of the project.

(b) Maintain a mechanism for dealing with complaints regarding the delivery of health services or performance of project activities.

(c) Hold confidential all information obtained by the personnel of the project from participants in the project related to their examination, care, and treatment, and shall not release such information without the individuals' consent except as may be required by law, as may be necessary to provide service to the individual, or as may be necessary to monitor the operations of this program or otherwise protect the public health. Information may be disclosed in a form which does not identify particular individuals.

(d) Utilize appropriate bookkeeping and accounting procedures and mechanisms to assure accountability for grant funds and resources.

(e) Operate with the approval, support, and involvement of the tribe, tribes, or Indian communities in the area served by the local facility and program.

(f) Provide Indians, to the extent feasible, opportunities for training and employment in connection with the administration of the project and also provide preference to Indians and Indian owned economic enterprises in the award of subcontracts in connection with the administration of the project.

(g) Keep in force adequate liability insurance in accordance with the approved application unless the Secretary, for good cause shown, determined that such insurance was not obtainable or appropriate or has determined that such insurance may be permitted to expire or lapse.

(h) Perform the project in accordance with the provisions of the Act and the regulations of this part.

(i) Provide services at a level and range which is not less than that provided by the Indian Health Service or that identified by the Service as an appropriate level, range, and standard of care.

§ 36.106 Grant award and evaluation.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants whose project will, in the judgment of the Secretary, best promote the purposes of the Act, and the regulations of this subpart, taking into account:

(1) The apparent capability of the applicant to organize and manage the proposed project successfully considering, among other things the adequacy of staff, management systems, equipment and facilities.

(2) The soundness of the applicant's plan for conducting the project and for assuring effective utilization of grant funds.

(3) The adequacy of the budget in relation to the scope of the project and available funds.

(4) The relative effectiveness of the applicant's plan, as set forth in the application, to carry out each of the requirements § 36.105.

(5) The compatibility of the proposed project with the published goals and responsibilities of the IHS in carrying out its statutory mission.

(b) All grant awards shall be in writing, shall set forth the amount of funds granted, and the period for which support is provided.

(c) Neither the approval of any project nor any grant award shall commit the United States in any way to make additional, supplemental, continuation or other awards with respect to any approved project or portion thereof.

§ 36.107 Use of Project Funds.

(a) Any funds granted pursuant to this subpart shall be expended solely for carrying out the approved project in accordance with section 104(b) of the Act, the regulations of this subpart, and the terms and conditions of award.

(b) The provisions of any other Act notwithstanding, any funds made available to a tribal organization under grants pursuant to section 104(b) of the Act may be used as matching shares for any other Federal grant programs which contribute to the purposes for which grants under this section are made.

§ 36.108 Funding duration.

The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for project costs and the availability of funds.

§ 36.109 Availability of appropriations.

The Secretary will from time to time publish a notice in the Federal Register indicating by areas the allotment of funds and categories of activities for which awards may be made under this subpart. The Secretary may revise such allotments and categories from time to time and will promptly publish a notice of such revisions in the Federal Register.

§ 36.110 Facilities construction.

In addition to other requirements of this subpart:

(a) An applicant for a construction grant to build, renovate, modernize, or remodel a hospital, clinic, health station or quarters for housing personnel associated with such facilities, must in its application:

(1) Provide its assessment of the environmental impact of the project as called for by section 102(2)(c) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(c)).

(2) Furnish its evaluation of the project site in accordance with the terms and conditions of E.O. 11296, 31 FR 10663 (August 10, 1966) relating to the evaluation of flood hazards in locating federally owned or financed facilities.

(b) Each applicant for construction grant to build, renovate, modernize, or remodel a hospital, clinic, health station or quarters for housing personnel associated with such facilities, in addition to any other requirements imposed by the Act or determined by the Secretary to be reasonably necessary with respect to particular projects to fulfill the purpose of the grant, shall be subject to the condition that the applicant shall furnish and comply with the following assurances:

(1) *Title.* That applicant has a fee simple or such other estate or interest in the site for construction, including necessary easements and rights-of-way, sufficient to assure for a period of not less than the estimated useful life of the facility undisturbed use and possession for the purpose of the construction and operation of the facility: *Provided, however,* That where the construction is to take place on land owned by the United States, applicant need not comply with this provision.

(2) *Competitive bids.* (i) That the approval of the Secretary shall be obtained before the project is advertised or placed on the market for bidding and that such approval shall include a determination by the Secretary that the final plans and specifications conform to the minimum standards of construction and equipment as set forth in Appendix A of this subpart.

(ii) That all contracting for construction (including the purchase and installation of built-in equipment) shall, except as provided in paragraph (b)(2)(iii) of this section or as provided in the regulations of this subpart or the Act be on a lump sum fixed-price basis, and contract will be awarded on the basis of competitive bidding obtained by public advertising with award of the contract to the lowest responsive and responsible bidder. The giving of preference to local contractors or suppliers over non-local contractors or suppliers, except as otherwise provided in these regulations is not authorized.

(iii) A substitute bidding procedure of selective solicitation with response from three or more bidders may be used if:

(A) The applicant requests and justifies the use of the procedure;

(B) The procedure is not inconsistent with applicable State or local laws; and

(C) The Secretary determines that it is necessary to limit bidding to contractors of proven competence due to the complexity or speciality of the project or that the time element is of primary consideration. When this bidding procedure is used the applicant shall establish reasonable bid prequalification standards for contractors. The applicant shall then accept and consider bids from any contractor who requests permission to bid and who is determined by applicant to meet these prequalification standards. Adequate time shall be allowed for contractors to prepare bids, and award of construction contracts shall be made to the lowest qualified and responsible bidder whose bid is considered fully responsive to the bid invitation.

(3) *Approval of estimated cost.* That the applicant will enter into no construction contract or contracts with respect to the project or any portion thereof where the cost exceeds the estimates in the application for such work, without prior approval of the Secretary.

(4) *Relocation assistance.* That in the case of an applicant with an approved project which involves the displacement of persons or businesses whose real property has or will be taken, the applicant will comply with the provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. 4601 and applicable regulations issued thereunder (45 CFR Part 15).

(5) *Completion responsibility.* The applicant will construct the project, or cause it to be constructed, to final completion in accordance with the grant application and the plans and specifications.

(6) *Progress reports.* That applicant shall furnish progress reports and such other information as the Secretary may require.

(7) *Construction supervision.* That applicant shall provide and maintain competent and adequate architectural and engineering supervision and inspection at the construction site to insure that the completed work conform to the plans and specifications.

(8) *Authorized uses.* That the facility is intended and will be used only for the purposes for which the application has been made.

(9) *Wage rate standards.* That all laborers and mechanics employed by contractors or subcontractors in the construction, alteration, or repair, including painting or decorating of building or other facilities in connection with contracts or grants entered into pursuant to the Act, shall be paid wages at not less than those prevailing on similar construction in the locality, as determined by the Secretary of Labor in accordance with the Davis-Bacon Act of March 3, 1931, as amended.

(10) *Accessibility by handicapped.* That the applicant shall require the facility to be designed to comply with the "American Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped," Number A 117.1—1961 as modified by other standards prescribed by the Secretary.

(11) *Minimum standards of construction and equipment.* That the plans and specifications for the project will conform to the minimum standards of construction and equipment as set forth in Appendix A of this subpart.

(12) *Construction contract requirements.* That the following conditions and provisions must be included in all construction contracts let by grantee:

(i) The provisions set forth in "DHHS Requirements for Federally Assisted Construction Contracts Regarding Labor Standards and Equal Employment Opportunities," Form DHHS 514 (latest edition) (issued by the Office of Grants Administration Policy, United States Department of Health and Human Services) pertaining to the Davis-Bacon Act, the Contract Work Hours and Safety Standards Act, and the Copeland Act (Anti-Kickback) Regulations, except in the case of contracts in the amount of $2,000 or less; and pertaining to Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, relating to nondiscrimination in construction contract employment, except in the case of contracts in the amount of $10,000 or less: *Provided, however,* That nothing required herein shall be in contravention of the requirements of section 7 of Pub. L. 93-638, 25 U.S.C. 450e.

(ii) The contractor shall furnish performance and payment bonds, each of which shall be in the full amount of the contract price, and shall maintain, during the life of the contract, adequate fire, workmen's compensation, public liability, and property damage insurance: *Provided, however,* That in the case of an Indian tribe or tribal organization entering into a construction contract of less than $100,000, State or local provisions with respect to performance and payment bonds shall be deemed to meet the requirements of this paragraph.

(iii) The Secretary shall have access at all reasonable times to work wherever it is in preparation or progress, and the contractor shall provide proper facilities for such access and inspection.

§ 36.111 Interest.

Tribes and Tribal organizations shall not be held accountable for interest earned on grant funds, pending disbursement by such organization.

§ 36.112 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

§ 36.113 Fair and uniform provision of services.

Services provided pursuant to a grant under this subpart shall be provided by the Grantee in a fair and uniform manner to all participants in the project consistent with their medical need, the policies and regulations of the Indian Health Service, and the Act.

§ 36.114 Applicability of 45 CFR Part 74.

The following provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles shall apply to all awards under this subpart to the extent they are consistent with this subpart:

(a) Subpart A "General", except that for purposes of this subpart the definition of "local government" in § 74.3 shall also include Indian tribes and tribal organizations.

(b) Subpart B, "Cash Depositories".

(c) Subpart C, "Bonding and Insurance" except as otherwise specifically provided in this subpart.

(d) Subpart D, "Retention and Custodial Requirements for Records".

(e) Subpart F, "Grant-Related Income", except for § 74.42.

(f) Subpart H, "Standards for Grantee and Subgrantee Financial Management Systems".

(g) Subpart I, "Financial Reporting Requirements".

(h) Subpart J, "Monitoring and Reporting of Program Performance".

(i) Subpart K, "Grant Payment Requirements", except that the references in § 74.94 to § 74.113 shall be deemed to be references to § 36.115 of this subpart.

(j) Subpart L, "Budget Revision Procedures".

(k) Sections 74.110 and 74.111 of Subpart M, "Grant Closeout, Suspension, and Termination".

(l) Subpart N, "Forms for Applying for Grants".

(m) Subpart O, "Property".

(n) Subpart P, "Procurement Standards" provided, however, that to the greatest extent feasible preferences and opportunities for training and employment in connection with the administration of grants and contracts pursuant to this Act shall be awarded to Indians and preference in the award of subcontracts and subgrants in connection with the administration of grants and contracts pursuant to this Act shall be given to Indian Organizations and Indian-owned economic enterprises.

(o) Sections 74.140 and 74.171 of Subpart Q, "Cost Principles," and Appendix C to such subpart, except for paragraph J (4) of Part I of such Appendix.

§ 36.115 Recission of grants.

(a) When the Secretary determines that the performance of a grantee under these regulations involves (1) the violation of the rights or endangerment of the health, safety, or welfare of any persons, or (2) gross negligence or the mismanagement in the handling or use of funds under the grant, the Secretary will, in writing, notify the grantee of such determination and will request that the grantee take such corrective action, within such period of time, as the Secretary may prescribe.

(b) When the Secretary determines that a grantee has not taken corrective action (as prescribed by him under paragraph (a) of this section) to his satisfaction, he may, after providing the grantee an opportunity for a hearing in accordance with paragraph (c) of this section, rescind the grant in whole or in part and if he deems it appropriate, assume or resume control or operation of the program, activity, or service involved.

(c) When the Secretary has made a determination described in paragraph (b) of this section, he shall in writing notify the grantee of such determination and of the grantee's right to request a review of such determination (and of the determination described in paragraph (a) of this section) under the Public Health Service Grant Appeals Procedure (42 CFR Part 50, Subpart D). Such notification by the Secretary shall set forth the reasons for the determination in sufficient detail to enable the grantee to respond and shall inform the grantee of its opportunity for review under such Subpart D. If the review held under Subpart D results in a response adverse to the grantee's position, the grantee shall be informed of its right to have a hearing before the Department Grant Appeals Board, pursuant to 45 CFR Part 16.

(d) Where the Secretary determines that a grantee's performance under a grant awarded under this subpart poses an immediate threat to the safety of any person, he may immediately rescind the grant in whole or in part and if he deems it appropriate, assume or resume control or operation of the program, activity, or service involved. Upon such recission he will immediately notify the grantee of such action and the basis or reasons therefor; and offer the grantee an opportunity for a hearing to be held within 10 days of such action. If the grantee requests such a hearing, the Secretary will designate three officers or employees of the Department to serve as a hearing panel. No officer or employee from the immediate office of the official who made the decision to rescind the grant under this paragraph may be designated to serve on the hearing panel.

(1) The hearing shall be commenced within 10 days after the recission of the grant, shall be held on the record and shall afford the grantee the right:

(i) To notice of the issues to be considered;

(ii) To be represented by counsel;

(iii) To present witnesses on grantee's behalf; and

(iv) To cross-examine other witnesses either orally or through written interrogatories.

(2) The hearing panel shall, within 25 days after the conclusion of the hearing, notify all parties in writing of its decision.

(3) Such decision shall not be subject to further hearing under 42 CFR Part 50, Subpart D or 45 CFR Part 16.

(e) In any case where the Secretary has rescinded a grant under paragraph (b) or (d) of this section, he may decline to enter into a new grant agreement with the grantee until such time as he is satisfied that the basis for the recission has been corrected. Nothing in this section shall be construed as contravening the Occupational Safety and Health Act of 1970 (84 Stat. 1590), as amended (29 U.S.C. 651).

(f) In any case where the Secretary has rescinded a grant for the delivery of health services under this subpart, the grantee shall, upon the request of the Secretary, transfer to the Secretary all medical records compiled in the operation of the supported project.

§ 36.116 Reports.

In addition to the reporting and information requirements provided in Subpart J of 45 CFR Part 74 made applicable to grants under this subpart by § 36.114, each recipient of Federal financial assistance shall make such reports and information available to the Indian people served or represented by such recipient as and in a manner determined by the Secretary to be adequate.

§ 36.117 Amendment of regulations.

Before revising or amending the regulations in this subpart, the Secretary shall take the following actions:

(a) Consult with Indian Tribes and national and regional Indian organizations to the extent practicable about the need for revision or amendment and consider their views in preparing the proposed revision or amendment.

(b) Present the proposed revision or amendment to the Committees on Interior and Insular Affairs of the United States Senate and House of Representatives.

(c) Publish the proposed revisions or amendments in the FEDERAL REGISTER as proposed rulemaking to provide adequate notice to receive comments from, all interested parties.

(d) After consideration of all comments received, publish the regulations in the FEDERAL REGISTER in final form not less than 30 days before the date they are made effective.

§ 36.118 Effect on existing rights.

The regulations in this part are not meant to and do not:

(a) Affect, modify, diminish, or otherwise impair the sovereign immunity from suit enjoyed by an Indian tribe;

(b) Authorize, require or permit the termination of any existing trust responsibility of the United States with respect to the Indian people;

(c) Permit significant reduction in services to Indian people as a result of this subpart.

§ 36.119 Penalties.

Section 6 of Pub. L. 93-638, 25 U.S.C. 450(d) provides:

Whoever, being an officer, director, agent, or employee of, or connected in any capacity with, any recipient of a contract, subcontract, grant, or subgrant pursuant to this Act or the Act of April 16, 1934 (48 Stat. 596), as amended, embezzles, willfully misapplies, steals, or obtains by fraud any of the money, funds, assets, or property which are the subject of such a grant, subgrant, contract, or subcontract, shall be fined not more than $10,000 or imprisoned for not more than two years, or both, but if the amount so embezzled, misapplied, stolen, or obtained by fraud does not exceed $100, he shall be fined not more than $1,000 or imprisoned not more than one year, or both.

§ 36.120 Use of Indian business concerns.

Grants awarded pursuant to this subpart will incorporate the following:

Use of Indian business concerns.

(a) As used in this clause, the term "Indian organizations of an Indian-owned economic enterprise" as defined in section 102(g) of this subpart.

(b) The grantee agrees to give preference to qualified Indian business concerns in the awarding of any contracts or subgrants entered into under the grant consistent with the efficient performance of the grant. The grantee shall comply with any preference requirements regarding Indian business concerns established by the tribe(s) receiving services under the grant to the extent that such requirements are consistent with the purpose and intent of this paragraph.

§ 36.121 Indian preference in training and employment.

(a) Any grant made under this subpart, or a contract or subgrant made under such a grant shall require that, to the greatest extent feasible preferences and opportunities for training and employment in connection with the administration of such grant, or contract or subgrant made under such grant, shall be given to Indians.

(b) The grantee shall include the requirements of paragraph (a) of this section in all contracts and subgrants made under a grant awarded under this subpart.

APPENDIX A—MINIMUM STANDARDS OF CONSTRUCTION AND EQUIPMENT

The minimum standards of construction and equipment set forth below have been established by the Secretary pursuant to section 107 of the Act (25 U.S.C. 450k). In accordance with 5 U.S.C. 542(a)(1), the publications to which reference is made in this Appendix A, unless otherwise indicated, are hereby incorporated by reference and made a part hereof. These documents are available for inspection at the Department's and Regional Officers'. Information Centers listed in 45 CFR 5.31 and copies of such documents may be purchased as specified. These standards are applicable to all proj-

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ects approved for construction grants under section 104(b)(1) of the Act; in addition, hospitals and outpatient facilities must comply with the requirements of "General Standards of Construction and equipment for Hospital and Medical Facilities" (DHHS Publication No. 74-4000) which document is incorporated by reference in § 53.101(a) of this chapter. Said document will be provided to all applicants with a need therefor, and is available to any interested person whetner or not affected by the provisions of this subpart, upon request to the Regional Office of the Department of Health and Human Services or the Public Inquiries Branch, Public Health Service, Washington, D.C.

(a) *General.* The structural design, construction, and fire safety provisions of all project facilities shall comply with the standards of the National Building Code, 1967 (available from American Insurance Association Engineering and Safety Department, 85 John Street, New York, NY 10037, or 120 South La Salle Street, Chicago, IL 60603, or 465 California Street, San Francisco, CA 94104) or with applicable State, local codes and ordinances, whichever is more restrictive.

(b) *Mechanical.* All installations of fuel burning equipment, steam, heating, air conditioning and ventilation, plumbing and other piping systems and boilers shall comply with the following standards:

(1) *Handbook of Fundamentals:* American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) 1972; United Engineer Center, 345 East 47th Street, New York, NY 10017.

(2) National Standard Plumbing Code 1955; American Society of Mechanical Engineers (ASME); United Engineer Center, 345 East 47th Street, New York, NY 10017.

(3) Boiler and Pressure Vessel Code, 1971 edition, with current addenda, section 8, Division I, American Society of Mechanical Engineers (ASME); United Engineer Center, 345 East 47th Street, New York, NY 10017.

(c) *Fire and safety.* The fire-resistant design criteria for the facility will be governed by the criteria necessary for that portion of the facility which is subject to the most severe usage. Remodeled structure shall be upgraded, in total, unless it is feasible to isolate the improved portion of the building with fire walls and fire doors. Fire-resistant design shall be in accordance with the standards of Fire Safety Code Number 101, 1970, National Fire Protection Association, International, 60 Batterymarch Street, Boston, MA 02110.

(d) *Emergency electrical service.* Fire alarm systems and other electrical service shall conform to the standards as specified in Life Safety Code Number 101, 1970, National Fire Protection Association, International, 60 Batterymarch Street, Boston, MA 02110.

(e) *Electrical.* All electrical installations and equipment shall be in accordance with State and local codes and applicable sections of National Electric Code, NFPA Bulletin No. 70 HC, 1971, National Fire Protection Association, International, 60 Batterymarch Street, Boston, MA 02110.

(f) *Radiation protection.* All areas in which X-ray, gamma-ray, beta-ray producing and similar equipment is located shall be protected from radiation in accordance with the standards which are in the handbook reports No. 33, 1968; 34, 1970; 35, 1970, and 36, 1970, of the National Council on Radiation Protection and Measurement, Box 4867, Washington, DC 20008.

(g) All facilities shall be designed and constructed in accordance with the standard specified in the Uniform Building Code, 1970, International Conference of Building Officials, 50 South Los Robles, Pasadena, CA 91101, unless more restrictive State and local codes govern.

(h) *Zoning.* Applicable State and local codes shall apply.

Subpart I—Contracts Under the Indian Self-Determination Act

AUTHORITY: Secs. 103, 107, 25 U.S.C. 450g, 450k; sec. 3, Pub. L. 83-568, 42 U.S.C. 2003.

SOURCE: 40 FR 53147, Nov. 14, 1975, unless otherwise noted.

§ 36.201 Policy and applicability.

(a) Policy. (1) The Congress has recognized the obligation of the United States to respond to the strong expression of the Indian people for self-determination by assuring maximum Indian participation in the direction of educational as well as other Federal services to Indian communities so as to render such services more responsive to the needs and desires of those communities.

(2) The Congress has declared its commitment to the maintenance of the Federal Government's unique and continuing relationship with the responsibilities to the Indian people through the establishment of a meaningful Indian self-determination policy which will permit an orderly transition from Federal domination of programs for and services to Indians to effective and meaningful participation by the Indian people in the planning,

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conduct, and administration of those programs and services.

(3) It is the policy of the Secretary of the Department of Health and Human Services to facilitate the efforts of Indian tribes to plan, conduct, and administer programs, or portions thereof, which the Indian Health Service is authorized to administer for the benefit of Indians.

(4) It is the policy of the Secretary to continually encourage Indian tribes to become increasingly knowledgeable about Indian Health Service programs and the opportunities Indian tribes have regarding them; however, it is the policy of the Indian Health Service to leave to Indian tribes the initiative in making requests for contracts and to regard self-determination as including the decision of an Indian tribe not to request contracts.

(5) It is the policy of the Indian Health Service not to impose sanctions on Indian tribes with regard to contracting or not contracting; however, the special resources made available to facilitate the efforts of those Indian tribes which do wish to contract should be made known to all tribes, as should the current realities of funding and Federal personnel limitations.

(6) Contracting is one of several mechanisms by which Indian tribes can exercise their right to plan, conduct, and administer programs or portions thereof which the Secretary is authorized to administer for the benefit of Indians. Another mechanism afforded Indian tribes is the use of a grant, as provided in Subpart H of this part, or other resources, to plan the manner in which it wishes the Indian Health Service to operate a program or portion thereof.

(7) The regulations in this subpart are not meant to and do not change the eligibility criteria which individuals must meet to be eligible for any program currently operated by the Indian Health Service.

(b) The regulations of this subpart are applicable to contracts awarded pursuant to section 103 of Pub. L. 93-638, 25 U.S.C. 450g to carry out any or all of the functions, authorities, and responsibilities of the Secretary of Health and Human Services under the Act of August 5, 1954 (68 Stat. 674), as amended, 42 U.S.C. 2001 et seq.

§ 36.202 Effect on existing rights.

The regulations in this subpart are not meant to and do not:

(a) Affect, modify, diminish, or otherwise impair the sovereign immunity from suit enjoyed by an Indian tribe.

(b) Authorize, require, or permit the termination of any existing trust responsibility of the United States with respect to the Indian people.

(c) Permit significant reduction in services to Indian people as a result of this subpart.

(d) Nothing in these regulations shall be construed to require a tribe to apply for a contract or contracts with the Secretary to carry out under the Indian Self-Determination Act any of the Secretary's functions, authorities and responsibilities under the Act of August 5, 1954, as amended, 42 U.S.C. 2001, et seq. Such applications under these regulations are voluntary.

(e) Nothing in these regulations shall be construed to preclude the making of contracts under any other authority of law nor to restrict contracts with Indian tribes or tribal organizations to contracts entered into under section 103 of the Act.

§ 36.203 Amendment of regulations.

Before revising or amending the regulations in this subpart, the Secretary will take the following actions:

(a) Consult with Indian tribes and national and regional Indian organizations to the extent practicable about the need for revision or amendment and consider their views in preparing the proposed revision or amendment.

(b) Present the proposed revision or amendment to the Committees on Interior and Insular Affairs of the United States Senate and House of Representatives.

(c) Publish the proposed revisions or amendments in the FEDERAL REGISTER as proposed rulemaking to provide adequate notice to receive comments from all interested parties.

(d) After consideration of all comments received, publish the regulations in the FEDERAL REGISTER in final form not less than 60 days before the date they are made effective.

§ 36.204 Definitions.

(a) "Act" means Title I of the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638 (25 USC 450f *et seq.*).

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) "Director" means the Director, Indian Health Service, Health Services Administration, Public Health Service, Department of Health and Human Services (IHS) who is the official to whom the Secretary has delegated full responsibility and authority to implement and administer those aspects of the Act related to the health and well-being of the Indian people.

(d) "Area Director" means the official in charge of an Indian Health Service Area, or Program Office.

(e) "Contracting Officer" means the person executing the contract on behalf of the Government and any other officer or employee who is properly designated Contracting Officer; and the term includes, except as otherwise provided in the contract, the authorized representative of the Contracting Officer acting within the limits of his authority.

(f) "Indian" means a person who is a member of an Indian tribe.

(g) "Indian Tribe" means any Indian tribe, band, nation, rancheria, Pueblo, colony or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) which is recognized as eligible by the United States Government for the special programs and services provided by the United States to Indians because of their status as Indians.

(h) "Tribal organization" means:

(1) The recognized governing body of any Indian tribe; or

(2) Any legally established organization of Indians which is:

(i) Controlled, sanctioned or chartered by such governing body or bodies; or

(ii) Democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities.

(i) "An Indian Owned Economic Enterprise" means any commercial industrial, or business activity established or organized for the purpose of profit which is not less than 51 percent Indian owned.

(j) An "Indian Self-Determination Contract Proposal" is the name of the document to be utilized by Indian Tribal organizations to forward to the Indian Health Service, their requests to enter into contracts for health programs or services.

(k) "Trust Resources" means natural resources, land, water, minerals, funds, or property, asset, or claim, including any intangible right or interest in any of the foregoing, which is held by the United States in trust for any Indian tribe or any Indian individual or which is held by any Indian tribe or Indian individual subject to a restriction on alienation imposed by the United States.

(l) "Trust Responsibility" means the responsibility assumed by the Government, by virtue of treaties, statutes and other means, legally associated with the role of trustee, to recognize, protect and preserve tribal sovereignty and to protect, manage, develop and approve authorized transfers of interests in trust resources held by Indian tribes and Indian individuals to a standard of the highest degree of fiduciary responsibility.

(m) "Retrocession" is the voluntary return of a contracted program, or portion thereof, to the Indian Health Service pursuant to section 106(d) of the Act.

(n) The Contract Proposal Declination Appeals Board (CPDAB) is a body established to review Indian Self-Determination Contract Proposals which have been disapproved.

CONTRACT PROPOSALS, REVIEW, AND APPEAL

§ 36.205 Eligibility and application.

(a) Any tribal organization upon the request of the Indian tribe to be served, is eligible to apply for a contract with the Secretary to carry out any or all of the functions, authorities and responsibilities of the Secretary under the Act of August 5, 1954.

(b) All such contracts shall be based upon Indian Self-Determination Contract proposals which will be specific and, as a minimum, include the following:

(1) Date Submitted.

(2) Full name and address of the Indian tribal organization submitting the proposal.

(3) Full name and tribe(s) which the tribal organization is affiliated with.

(4) Narrative description of the functions, IHS programs, or portions thereof which the tribal organization wants to contract for.

(5) Type of contract proposed (cost reimbursement, fixed price, etc.).

(6) Proposed contract starting and completion dates.

(7) Equipment and facilities needed to carry out the contract and how the tribal organization intends to obtain such.

(8) Narrative indicating the tribal organization's knowledge of the program or function or portion thereof to be contracted for and the relation of such to the mission of the Indian Health Service. Where tribal organizations have already been involved in a contract for such programs, this narrative may be in the form of an updated version of the scope of work under that contract. In any case, the following items should be described in the narrative:

(i) Experience and training of personnel performing under the contract;

(ii) Familiarity with Federal Regulations and procedures involved;

(iii) Experience in operating a similar or related tribal program;

(iv) Extent of subcontracting contemplated and, where such information is available, identification of proposed subcontractors;

(v) Identification of Federal employee transfers contemplated;

(vi) Personnel system and key personnel;

(vii) The work plan for carrying out the contract including the timetable for delivery of optimum services.

(9) Evidence of community support for or lack of opposition to the contract.

(10) Information concerning training to be given to personnel who will perform under the contract.

(11) Estimate of the number of Indians to be served.

(12) A budget, including separate cost estimates for salaries and wages, equipment, supplies, services, travel, subcontracts, other direct costs and overhead.

(13) Justification and request for advance payments.

(14) Names and telephone numbers of the tribal organization's business and technical personnel who may be contacted during the evaluation and negotiation process.

(15) A description of the tribal organization including:

(i) The legal and organizational relationship of the tribal organization to the Indians in the area to be served or effected by the contract.

(ii) A description of the participation of Indians in all phases of the tribal organization.

(iii) Whether the tribal organization is controlled, sanctioned or chartered by the governing body of Indians to be served, and, if so, evidence of such fact.

(iv) And, if elected, a description of the election process, voting criteria, and extent of voter participation.

(16) Evidence of adequate liability insurance coverage or an explanation of why such insurance cannot or should not be obtained. Such insurance shall provide that prior to cancellation the Secretary must be notified and must further provide that each such policy of insurance shall contain a provision that the insurance carrier shall waive any right it may have to raise as a defense the tribe's sovereign immunity from suit but such waiver shall extend only to claims the amount and nature of which are within the coverage and limits of the policy and shall not authorize or empower such insurance carrier to waive or otherwise limit the Tribe's sovereign immunity outside or beyond the coverage and limits of the policy of insurance.

(17) The intended financial participation, if any, of the tribal organization or the tribes to be served specifying the type of contributions such as cash or services, loans of full or part-time staff, equipment, space, materials, or facilities, or other contributions.

(18) Specifically include any requests for waivers to 41 CFR Chapter 1 and 3 in accordance with 36.216.

(c) The Indian Self-Determination Contract Proposal shall be executed by a person or persons authorized to act on behalf of the tribal organization and shall be accompanied by evidence that such person or persons are authorized to bind the tribal organization.

(d) The Indian Self-Determination Contract Proposal should be addressed to the Area Director of the appropriate Indian Health Service Area. Such proposals should be submitted, in 5 copies, well in advance of the desired beginning of support.

(e) Tribal organizations may obtain assistance in preparing Indian Self-Determination contract proposals from the IHS Area Offices. The Area Directors shall make any information available to the tribal organization which is needed in the preparation of its proposal except as may be exempt from disclosure by the Freedom of Information Act, 5 U.S.C. 552(b) and the Department of Health and Human Services regulations thereunder, 45 CFR, Part 5.

§ 36.206 Tribal clearances—initial contracts.

(a) Before the IHS may enter into a contract with a tribal organization, it must be requested to do so by the tribe. The tribe's request shall be in the form of a resolution by the tribal governing body. If the tribal organization is applying for a contract to perform services benefiting more than one tribe, an authorizing resolution from each tribal governing body must be obtained before submitting the application to IHS for approval. A tribal governing body may pass a single resolution authorizing a tribal organization to apply for, negotiate, and execute more than one contract if the resolution specifies for each contract the same information required in paragraphs (b) and (c) of this section.

(b) The resolution of the tribal governing body shall authorize the applicant tribal organization to apply for, negotiate and contract with the IHS subject to the specific terms, conditions and limitations of the resolution and applicable tribal laws, codes, and regulations and custom. The resolution shall include the date the resolution was approved, and signature of the person authorized to certify the accuracy of the information contained in the resolution.

(c) The tribal governing body's request (resolution) should include the following:

(1) When the tribal organization is the tribal governing body:

(i) A brief statement of the contract scope.

(ii) The tribal official authorized to negotiate the contract and any amendments thereto.

(iii) The tribal official authorized to execute the contract and any amendments thereof.

(iv) The expiration date of the authorities granted by the resolution.

(v) The extent and procedure, if any, for review of the contract and any amendments thereto by the tribal governing body before execution.

(vi) The proposed date for contract commencement.

(vii) The proposed term of the contract.

(2) When the tribal organization is other than the tribal governing body:

(i) The name of the tribal organization.

(ii) A brief statement of the contract scope.

(iii) The extent and procedure, if any, for review by the tribal governing body of the contract and any amendments thereto prior to execution by the tribal organization.

(iv) The tribal office or official to which the IHS should send copies of contract documents and correspondence.

(v) The proposed term of the contract.

(vi) The proposed date for contract commencement.

(vii) Any limitations on authorities granted the tribal organization.

(d) Any procedures specified in this section concerning the manner in which a tribal governing body passes a tribal resolution shall apply except where inconsistent with tribal constitution, law, code, ordinance, or custom. In such cases, the tribal law or procedures shall be cited in the resolution and shall take precedence.

§ 36.207 Tribal clearances—renewal contracts.

The Secretary may renew a contract for the same function(s) or programs as the original contract at the written request of the tribal organization designated in the tribal resolution. Requests for contract renewals shall be made as follows:

(a) If the original contract provided services to only one Indian tribe, written applications for renewal shall be sent by the tribal organization to the Area Office as follows:

(1) Directly, when the tribal organization involved is the governing body of the tribe.

(2) Through the governing body of the tribe for review when the tribal organization is not the governing body of the tribe. Submission shall be made to the governing body at least 75 calendar days before the original contract expires. The tribal organization shall promptly notify the IHS Area Office in writing of the date the tribal governing body received the application. If, within 45 calendar days after receiving the application, the tribal governing body does not provide the IHS Area Director with a formal resolution objecting to the application for renewal, the absence of receipt of such a resolution shall constitute the tribe's request for renewal of the contract.

(b) If the original contract provided services to more than one Indian tribe, the tribal organization must give a copy of the written application for renewal to each tribal governing body at least 75 calendar days before the original contract expires. The tribal organization shall promptly notify the IHS Area Office where the application is to be submitted in writing, of the date the tribal governing bodies received copies of the application. If, within 45 calendar days after receiving copies of the application none of the tribal governing bodies provide the appropriate IHS Area Office with a formal resolution objecting to the application for renewal, the absence of receipt of such resolutions shall constitute the tribes' request for renewal of the contract. If one or more of the tribal governing bodies involved object to the renewal, the contract will not be made until all the tribal governing bodies have approved the request or the matter is otherwise resolved.

§ 36.208 Evaluation criteria.

(a) Indian Self-Determination Contract Proposals will be evaluated to determine:

(1) If the service to be rendered to Indian people by the proposed contract will be satisfactory;

(2) If the proposed contract will assure that trust resources are protected; and

(3) If the proposed contract will ensure proper completion and maintenance of the project or function involved. Failure to meet any of the above, may be cause for declination of the Indian Self-Determination Contract Proposal. However, the burden of proof to show cause for declination lies with the approving official.

(b) To determine if an Indian Self-Determination Contract Proposal meets the above criteria, the Area Director and his staff will consider whether the tribal organization would be deficient in performance under the contract with respect to the factors listed in this paragraph.

(1) *Equipment, buildings and facilities.* No higher standards with regard to buildings, facilities, or equipment shall be applied to tribal organizations than have previously been applied to IHS. The Indian Health Service shall make available the use of all equipment which has been allocated to the operation of the program by the IHS in the past, unless the IHS determines that the provision of such equipment will seriously interfere with the IHS's ability to provide services to Indian people in noncontracted programs. Where equipment is shared by the programs to be contracted and other non-contracted programs, equipment-

sharing or other suitable arrangements will be reflected in the contract.

(2) *Bookkeeping and accounting procedures.* It must be clearly established by the Indian Health Service that the tribal organization which will undertake the contract does have an adequate accounting and bookkeeping system. IHS may assist the contractor in establishing an acceptable bookkeeping and accounting system.

(3) *Substantive knowledge of the program to be contracted.* The tribal organization shall be presumed to have substantive knowledge of the program to be contracted if it meets one or more of the following conditions:

(i) The tribal organization has successfully managed a similar program before through grant or contract for which standards have been established.

(ii) The members of the tribal organization have been consumers of such services in the past and have developed an understanding of the program sufficient to enable the tribal organization to effectively carry out the contract operation.

(iii) The tribal organization has made arrangements to obtain and to develop its knowledge of the program.

(4) *Community support.* Before the IHS can enter into a contract there must be a request made in accordance with § 36.206. The tribal governing body's resolution under § 36.206 shall be presumed to demonstrate that there is community support for the proposed contract. Any assertion of a lack of community support by persons to be served under the contract, is subject to exhaustion of tribal remedies by those making such assertions.

(5) *Adequacy of trained personnel.* The adequacy of trained personnel available to the tribal organization to carry out the proposed contract will be presumed if any of the following conditions exists:

(i) If the tribal organization has a personnel system that prescribes minimum occupational qualification standards, which shall be not less than minimum Civil Service standards where applicable and procedures for the selection of personnel on the basis of such qualifications, and the personnel to be used under the proposed contract are to be employed under the personnel system.

(ii) If there is no tribal personnel system, it will be assumed that the personnel to be employed under the proposed contract are adequately trained if the tribal organization has established position descriptions for key personnel to be employed under the contract and will establish within a reasonable time a personnel system similar to the one described in paragraph (c)(5)(i) of this section.

(6) *Other necessary components of contract performance.* (i) The contractor's proposal must demonstrate the capacity to meet minimum health program and professional standards established by IHS for each major health service activity of the IHS. The Director will establish and make available to any prospective contractor the minimum standards for each major health service activity of the Indian Health Service. In evaluating the contractor's proposal, the IHS will take into account the prevailing health program and professional standards of IHS for the health service activity in the location concerned.

(ii) The contractor's proposal will be evaluated to determine the contractor's ability to meet the Uniform Administrative Standards published as a Notice of Proposed Rulemaking in February 10, 1975, 40 FR 6304.

(iii) The ability of the contractor to carry out the contract in accordance with IHS policy, the applicable regulations of this part, and the Act.

(iv) No other components shall be prescribed as a basis for declination unless such components are added to the regulations in this subpart by revision or amendment of regulations.

(7) IHS officials may not decline to enter into a contract with a tribal organization because of any objection that would be overcome through the contract.

§ 36.209 Government property.

(a) In carrying out a contract made under this part, the Director will wherever possible, permit a tribal contractor to use buildings, facilities, and related equipment and other personal property owned by the IHS within his jurisdiction. Arrangements on the use of IHS property shall be provided for in the contract or other agreement as appropriate. In determining whether real or personal property can be provided, he shall determine whether the IHS can provide comparable services for any of the uncontracted part of the program.

(b) Requests for the use of IHS property which arise after signing of the contract shall be submitted to the relevant IHS official by the tribal organization. Such requests should be granted unless such a use would seriously interfere with the administration of existing IHS programs. The property must conform to the minimum standards established pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651).

§ 36.210 Submitting contract proposals.

(a) When services under the proposed contract will be provided to one or more tribes within the jurisdiction of a single Area Office, the completed contract proposal with documentation of the tribal request(s) and approvals of each such tribe effected shall be delivered or mailed to the Area Director of that Area Office.

(b) When services will be provided to tribes within the jurisdiction of more than one IHS Area Office, a copy of such proposals and documentation shall be forwarded to each of the Area Offices affected.

§ 36.211 Contract proposal approval officials.

The Director or his delegate is authorized to approve proposals for contract under this subpart.

§ 36.212 Review.

Upon receiving a contract application, Indian Health Service will:

(a) Notify the tribal organization in writing that the proposal has been received. This notice will be made within five (5) calendar days after receipt of the proposal.

(b) Review the proposal for completeness and promptly request additional information from the tribal organization or from the requesting tribe which will be needed to reach a decision.

(c) Notify Area Office subordinate activities serving the tribe(s) which will receive services under the contract and obtain any needed information and/or relevant recommendations on the contract.

(d) Assess the contract proposal to determine if it is feasible and if it complies with the appropriate requirements of the Act and of the regulations in this subpart.

(e) Meet with representatives of the tribal governing body and contract applicant to resolve any declination issues.

(f) Whenever declination issues cannot be resolved as in paragraph (e) of this section, notify the tribal organization of deficiencies in the proposal and provide to the extent practicable technical assistance, as requested, to overcome such deficiencies.

(g) Approve or disapprove the proposal after fully reviewing and assessing it and any additional information submitted by the tribal organization provided, however, that no action to disapprove shall be taken during the period of provision of technical assistance.

(h) Promptly notify the tribal organization in writing of the decision to approve or disapprove the proposal. If the proposal is disapproved, the notice shall contain but need not be limited to the following:

(i) Specific objections, which are based on failures to meet applicable program or administrative standards or fund restrictions, which preclude acceptance of the Indian Self-Determination Contract Proposal;

(ii) Guidance to the tribe regarding the steps which need to be taken to overcome the stated objections;

(iii) Identification of assistance which can practicably be made available to the tribe upon request to overcome the stated objections;

(iv) Notification to the tribal organization of its right to appeal and to request an informal or formal hearing in accordance with § 36.214 of this subpart.

§ 36.213 Processing time.

The approving official will approve or disapprove a contract proposal within sixty (60) calendar days after receipt. The sixty (60) calendar day deadline may be extended only after obtaining the written consent of the tribal organization.

§ 36.214 Tribal appeals to proposal declinations.

(a) On being advised that an Indian Self-Determination Contract Proposal has been disapproved by the appropriate approving official, and having been informed of the basis of such decision, the tribal organization may file a written appeal to the Contract Proposal Declination Appeals Board within thirty (30) days after receipt of the Declination Notice and may request an informal or formal hearing. The written appeal should either refute or overcome the objections stated as a basis for disapproval. The Contract Proposal Declination Appeals Board shall consider such an appeal, conduct any requested hearing thereon, and recommend a decision to the Director, Indian Health Service, or his representative whose decision shall be final.

(b) (1) The tribal organization and the Indian tribe or tribes affected shall be notified, in writing, of the date, time, place, and purpose of the hearing. The hearing will be conducted within 30 calendar days of written request for a hearing or at such later time as may be agreed upon. The IHS will authorize payment of transportation costs and per diem to allow adequate representation of the applicant, if the meeting is more than 50 miles from the office of the applicant.

(2) The hearing may be held under such rules as may be agreed upon.

(c) If formal hearing is requested, it will be conducted within thirty (30) calendar days from receipt of the written request for a hearing or at such later time as may be agreed upon, and the notice of hearing shall specify in writing the date, time, place, and purpose of the hearing and shall afford the tribe or tribal organization the right:

(1) To written notice of the issues to be considered;

(2) To be represented by counsel;

(3) To written record of the hearing;

(4) To present and cross-examine witnesses;

(5) To file written statements prior to the hearing;

(6) To compel the appearance of Indian Health Service personnel or to take depositions of such persons at reasonable times and places.

(d) The decision of the Director, IHS, or his representative on the appeals will be rendered within 15 calendar days from the date of receipt by the Director of the IHS of the Board's recommendation.

(e) The Contract Proposal Declination Appeals Board shall be composed of 5 members appointed by the Director, Indian Health Service, one of whom shall be designated to serve as Chairman.

PROCUREMENT

§ 36.215 Applicability of regulations.

Contracts with tribal organizations resulting from the submission of Indian Self-Determination Contract Proposals as authorized in Pub. L. 93-638 shall be in accordance with Chapters 1 and 3 of 41 CFR.

§ 36.216 Waivers.

(a) The Secretary may, for good cause shown, waive for the purposes of a specific contract any federal contracting laws and regulations which he determines are not appropriate for the purposes of the contract involved or are inconsistent with the Act.

(b) Requests for waivers may be initiated by tribal organizations or IHS contracting officers. Such requests will be forwarded to the Director, IHS for decision or further processing to the Secretary as required.

(c) A waiver request shall set forth clearly and precisely the following:

(1) The nature and basis of the needed waiver;

(2) Identification of the procurement regulation provision from which the waiver is needed;

(3) The circumstances under which the waiver would be used;

(4) The intended effect of the waiver;

(5) The length of time for which it can be anticipated that the waiver will be required;

(6) Reasons which will contribute to complete understanding and support of the requested waiver;

(7) Copies of pertinent background papers such as forms, contractor requests, etc.

(d) Whenever a waiver is requested by a tribal organization and such request is denied, the tribal organization will be notified of the reasons for denial.

§ 36.217 Fair and equal treatment of Indian people.

Contracts awarded to tribal organizations pursuant to the Indian Self-Determination Act shall incorporate the following clause:

The Contractor agrees, consistent with medical need, to make no discriminatory distinctions among Indian patients or beneficiaries of this contract. For the purpose of this contract discriminatory distinctions include but are not limited to the following:

(a) Denying a patient any service or benefit or availability of a facility;

(b) Providing any service or benefit to a patient which is different, or is provided in a different manner or at a different time from that provided to other patients under this contract; subjecting a patient to segregation or separate treatment in any manner related to his receipt of any service; restricting a patient in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service benefit; treating a patient differently from others in determining whether he satisfies any admission, enrollment, quota, eligibility membership, or other requirements or condition which individuals must meet in order to be provided any service or benefit; the assignment of times or places for the provision of services on the basis of discriminatory distinctions which may be made of the patients to be served.

§ 36.218 Types of contracts.

Cost-reimbursement type contracts provide for payment to the contractor of allowable costs incurred in the performance of the contract, to the extent prescribed in the contract: This type of contract establishes an estimate of total cost for the purpose of obligation of funds, and a monetary ceiling which the contractor may not exceed. Except as provided below, cost reimbursement contracts will be used for all contracts made pursuant to this subpart. A negotiated cost reimbursement contract shall contain the terms set out in § 3-4.6013 of 41 CFR.

(a) Fixed-price contracts may be used in those instances where costs can be precisely established. A negotiated fixed-price contract shall contain the terms set out in § 3-4.6014 of 41 CFR.

(b) Cost sharing contracts may be used where the tribe contributes to the cost of a program and may specify a percentage of cost or fixed amount to be funded by the government.

§ 36.219 Term of contract.

(a) The term of contracts awarded under the Acts shall normally be for one year except that contracts may be made for a longer term up to three years subject to the availability of appropriations under the following circumstances:

(1) The services provided under the contract can reasonably be expected to be continuing in nature and, as a result, a longer contract term would be advantageous.

(2) The Indian tribe or tribes to be served by the contract request that the term be more than one year. The tribal organization will indicate the desired term of the contract in the Self-Determination Contract Proposal.

(b) Contracts made for a term of more than one year may be renegotiated annually to reflect factors which include, but need not be limited to, cost increases beyond the control of the tribal contractor. Proposed changes in the services provided under the contract which reflect changes in program emphasis may be considered during the annual renegotiation if the changes fall within the general scope of the contract.

§ 36.220 Use of Indian business concerns.

Contracts awarded under authority of the Act shall incorporate the following clause, which is also set forth in 41 CFR 3-4.6013 and 3-4.6014.

(a) As used in this clause, the term "Indian business concern" means Indian organizations or an Indian-owned economic enterprise as defined in 42 CFR 36.204(i).

(b) The contractor agrees to give preference to qualified Indian business concerns in the awarding of any subcontracts entered into under the contract consistent with the efficient performance of the contract. The contractor shall comply with any preference requirements regarding Indian business concerns established by the tribe(s) receiving services under the contract to the extent that such requirements are consistent with the purpose and intent of this paragraph.

(c) If no Indian business concerns are available under the conditions in paragraph (b) above, the contractor agrees to accomplish the maximum amount of subcontracting, as the contractor determines is consistent with its efficient performance of the contract, with small business concerns, labor surplus area concerns or minority business enterprises, the definitions for which are contained in Subparts 1-1.7, 1-1.8, and 1-1.13 of the Federal Procurement Regulations. The contractor is not, however, required to establish a small business, labor surplus, or minority business subcontracting program as described in §§ 1-1.710-3(b), 1-1.805-3(b) and 1-1.1310-2(b), respectively of the Federal Procurement Regulations (41 CFR 1).

§ 36.221 Indian preference in training and employment.

Contracts awarded under authority of the Act shall incorporate the following clause, which is also set forth in 41 CFR 3-4.6013 and 3-4.6014.

INDIAN PREFERENCE IN TRAINING AND EMPLOYMENT

(a) The contractor shall give preference in employment for all work performed under the contract, including subcontracts thereunder, to qualified Indians regardless of age, religion or sex and, to the extent feasible consistent with the efficient performance of the contract, provide employment and training opportunities to Indians, regardless of age, religion or sex that are not fully qualified to perform under the contract. The contractor shall comply with any Indian preference requirements established by the tribe receiving services under the contract to the extent that such requirements are consistent with the purpose and intent of this paragraph.

(b) If the contractor or any of its subcontractors is unable to fill its employment openings after giving full consideration to Indians as required in paragraph (a) above, these employment openings may then be filled by other than Indians under the conditions set forth in the Equal Opportunity clause of this contract.

(c) The contractor agrees to include this clause or one similar thereto in all subcontracts issued under the contract.

§ 36.222 Indemnity and insurance.

Contracts awarded under authority of the Act shall incorporate the following clause, which is also set forth in 41 CFR 3-4.6013 and 3-4.6014.

(a) The Contractor shall indemnify and save and keep harmless the Government against any or all loss, cost, damage, claim, expense or liability whatsoever, because of accident or injury to persons or property or others occurring in connection with any program included as a part of this contract, by providing where applicable, the insurance described below.

(b) The Contractor shall secure, pay the premium for, and keep in force until the expiration of this contract, or any renewal period thereof, insurance as provided below. Such insurance policies shall specifically include a provision stating the liability assumed by the Contractor under this contract.

(1) Workmen's compensation insurance as required by laws of the State.

(2) Owner's, landlord's and tenant's bodily injury liability insurance with limits of not less than $50,000 for each person and $500,000 for each accident.

(3) Property damage liability insurance with limits not less than $25,000 for each accident.

(4) Automobile bodily injury liability insurance with limits of not less than $50,000 for each person, and $500,000 for each accident and property damage liability insurance with a limit of not less than $5,000 for each accident.

(5) Food products liability insurance with limits of not less than $50,000 for each person and $500,000 for each accident.

(6) Professional malpractice insurance where medical, dental or other health professional services are involved.

(7) Other liability insurance not specifically mentioned when required.

(c) Each policy of insurance shall contain an endorsement providing that cancellation by the insurance

BEST DOCUMENT AVAILABLE

company shall not be effective unless a copy of the cancellation is mailed (registered) to the Contracting Officer 30 days prior to the effective date of cancellation.

(d) A certificate of each policy of insurance, and any change therein, shall be furnished to the Contracting Officer immediately upon receipt from the insurance company.

(e) Insurance companies of the Contractor shall be satisfactory to the Contracting Officer. When in his opinion an insurance company is not satisfactory for reasons that will be stated, the Contractor shall provide insurance through companies that are satisfactory to the Contracting Officer.

(f) Each policy of insurance shall contain a provision that the insurance carrier waives any rights it may have to raise as a defense the tribe's sovereign immunity from suit, but such waiver shall extend only to claims the amount and nature of which are within the coverage and limits of the policy of insurance. The policy shall contain no provision, either expressed or implied, that will serve to authorize or empower the insurance carrier to waive or otherwise limit the tribe's sovereign immunity outside or beyond the coverage and limits of the policy of insurance.

§ 36.223 Exemption from bonds.

A tribal organization is not required to furnish performance and payment bonds before carrying out a contract under this part for the construction of public buildings or works as required by the Miller Act of August 24, 1935 (49 Stat. 793), as amended. However, the tribal organization shall require each of its subcontractors, other than tribal organizations, to furnish both performance and payment bonds as follows:

(a) A performance bond with a surety or sureties satisfactory to the approving official, and in an amount he deems adequate, for the protection of the United States.

(b) A payment bond with a surety or sureties satisfactory to the approving official for the protection of all persons supplying labor and material in carrying out the contract the use of each person. Whenever the total amount payable by the terms of the contract is not more than $1,000,000 the payment bond shall be one-half the total amount payable by the terms of the contract. Whenever the total amount payable by the terms of the contract is more than $1,000,000 but not more than $5,000,000, the payment bond shall be 40 percent of the total amount payable by the terms of the contract. Whenever the total amount payable by the terms of the contract is more than $5,000,000 the payment bond shall be $2,500,000.

§ 36.224 Construction and architect-engineering contracts.

The special provisions, procedures, and requirements applicable to construction and architect-engineering service contracts are set forth in § 3-4.6008 of 41 CFR.

§ 36.225 Performance of personal services.

Any contract made under this subpart may include provisions for the performance of personal services which would otherwise be performed by Federal employees. Such services include, but are not limited to, performing the following functions in connection with the contract and applicable rules and regulations:

(a) Determining the eligibility of applicants for assistance, benefits, or services.

(b) Determining the extent or amount of assistance, benefits, or services to be provided.

(c) Providing such assistance, benefits, or services.

§ 36.226 Advance payments.

Contracts awarded under the authority of the Act shall incorporate the following clause, which is also set forth in 41 CFR 3-4.6013 and 3-4.6014.

(a) *Amount of advance.* At the request of the contractor, and subject to the conditions hereinafter set forth, the Government shall make an advance payment, or advance payments from time to time, to the Contractor. No advance payment shall be made (1) without the approval of the officer administering advance payments (hereinafter called the "Administering Office" and designated in paragraph (k)(4) hereof) to the financial necessity therefore; (2) in an amount which together, as with all advance payments theretofore made, shall exceed the amount stated in paragraph (k)(1) of this section; and (3) without a properly certified invoice or invoices.

(b) *Special Bank Account.* Until all advance payments made hereunder are liquidated and the Administering Office approves in writing the release of any funds due and payable to the Contractor, all advance payments and all other payments under the contract shall be made by check payable to the Contractor, and be marked for deposit only in a Special Bank Account with the bank designated in paragraph (k)(2) of this section. No part of the funds in the Special Bank Account shall be mingled with other funds of the contractor prior to withdrawal thereof from the Special Bank Account as hereinafter provided. Except as hereinafter provided, each withdrawal shall be made only by check of the Contractor countersigned on behalf of the Government by the Contracting Officer or such other person or persons as he may designate in writing (hereinafter called the "Countersigning Agent"). Until otherwise determined by the Administering Office, countersignature on behalf of the Government will not be required.

(c) *Use of Funds.* The funds in the Special Bank Account may be withdrawn by the Contractor solely for the purposes of making payments for items of allowable cost or to reimburse the Contractor for such items of allowable cost, and for such other purposes as the Administering Office may approve in writing. Any interpretation required as to the proper use of funds shall be made in writing by the Administering Office.

(d) *Return of funds.* The Contractor may at any time repay all or any part of the funds advanced hereunder. Whenever so requested in writing by the Administering Office, the Contractor shall repay to the Government such part of the unliquidated balance of advance payments as shall in the opinion of the Administering Office be in excess of current requirements, or (when added to total advance previously made and liquidated) in excess of the amount specified in paragraph (k)(1) of this section. In the event the Contractor fails to repay such part of the unliquidated balance of advance payments when so requested by the Administering Office, all or any part thereof may be withdrawn from the Special Bank Account by checks payable to the Treasurer of the United States signed solely by the Countersigning Agent and applied in reduction of advance payments then outstanding hereunder.

(e) *Liquidation.* If not otherwise liquidated, the advance payments made hereunder shall be liquidated as herein provided. When the sum of all payments under this contract, other than advance payments, plus the unliquidated amount of advance payments are equal to the total estimated cost for the work under this contract or such lesser amount to which the total estimated cost under this contract may have been reduced, plus increases, if any, in this total estimated cost not exceeding, in the aggregate (including, without limitation, reimbursable costs incident to termination for cause and retrocession as estimated by the Contracting Officer), the Government shall thereafter withhold further payments to the Contractor and apply the amounts withheld against the Contractor's obligation to repay such advance payments until such advance payments shall have been fully liquidated. If upon completion, termination, or retrocession of the contract all advance payments have not been fully liquidated, the balances therefore shall be deducted from any sums otherwise due or which may become due to the Contractor from the Government, and any deficiency shall be paid by the Contractor to the Government upon demand.

(f) *Bank Agreement.* Before an advance payment is made hereunder, the Contractor shall transmit to the Administering Office, in the form prescribed by such office, an Agreement in triplicate from the bank in which the Special Bank Account is established, clearly setting forth the special character of the account and the responsibilities of the bank thereunder. Wherever possible, such bank shall be a member bank of the Federal Reserve

System, or an "insured" bank within the meaning of the Act creating the Federal Deposit Insurance Corporation Act of August 23, 1935, 49 Stat. 685, as amended (12 U.S.C. 264).

(g) *Lien on Special Bank Account.* The Government shall have a lien upon any balance in the Special Bank Account paramount to all other liens, which lien shall secure the repayment of any advance payments made hereunder.

(h) *Lien on property under contract.* Any and all advance payments made under this contract shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, upon the supplies or other things covered by this contract and on all material and other property acquired for or allocated to the performance of this contract, except to the extent that the Government by virtue of any other provision of this contract, or otherwise, shall have valid title to such supplies, materials, or other property as against other creditors of the Contractor. The Contractor shall identify, by marking or segregation, all property which is subject to a lien in favor of the Government by virtue of any provision of this contract in such a way as to indicate that it is subject to such lien and that it has been acquired for or allocated to the performance of this contract. If for any reason such supplies, materials, or other property are not identified by marking or segregation, the Government shall be deemed to have a lien to the extent of the Government's interest under this contract on any mass of property with which such supplies, materials, or other property are commingled. The Contractor shall maintain adequate accounting control over such property on his books and records. If at time during the progress of the work on the contract it becomes necessary to deliver any item or items and materials upon which the Government has a lien as aforesaid to a third person, the Contractor shall notify such third person of the lien herein provided and shall obtain from such third person a receipt, in duplicate, acknowledging, inter alia the existence of such lien. A copy of each receipt shall be delivered by the Contractor to the Contracting Officer. If this contract is terminated in whole or in part and the Contractor is authorized to sell or retain termination inventory acquired for or allocated to this contract, such sale or retention shall be made only if approved by the Contracting Officer, which approval shall constitute a release of the Government's lien hereunder to the extent that such termination inventory is sold or retained, and to the extent that the proceeds of the sale, or the credit allowed for such retention on the Contractor's termination claim, is applied in reduction of advance payments then outstanding hereunder.

(i) *Insurance.* The Contractor represents and warrants that he is now maintaining with responsible insurance carriers, (1) insurance upon his own plant and equipment against fire and other hazards to the extent that like properties are usually insured by others operating plants and properties of similar character in the same general locality; (2) adequate insurance against liability on account of damage to persons or property; and (3) adequate insurance under all applicable workmen's compensation laws. The Contractor agrees that, until work under this contract has been completed and all advance payments made hereunder have been liquidated, he will (i) maintain such insurance; (ii) maintain adequate insurance upon any materials, parts, assemblies, subassemblies, supplies, equipment and other property acquired for or allocable to this contract and subject to the Government lien hereunder; and (iii) furnish such certificates with respect to his insurance as the Administering Office may from time to time require.

(j) *Prohibition against assignment.* Notwithstanding any other provision of this contract, the Contractor shall not transfer, pledge, or otherwise assign this contract, or any interest therein, or any claim arising thereunder, to any party or parties, bank, trust company, or other financing institution.

(k) *Designations and determinations*—(1) *Amount.* The amount of advance payments at any time outstanding hereunder shall not exceed $———.

(2) *Depository.* The bank designated for the deposit of payments made hereunder shall be:

(3) *Interest charge.* No interest shall be charged for advance payments made hereunder. The Contractor shall charge interest at the rate of 6 percent per annum on subadvances or down payments to subcontractors, and such interest will be credited to the account of the Government. However, interest need not be charged on subadvances on nonprofit subcontracts with nonprofit educational or research institutions for experimental, research or development work.

(4) *Administering Office.* The office administering advance payments shall be the office designated as having responsibility for awarding the contract.

(l) *Other security.* The terms of this contract shall be considered adequate security for advance payments hereunder, except that if at any time the administering Office deems the security furnished by the Contractor to be inadequate, the Contractor shall furnish such additional security as may be satisfactory to the Administering Office, to the extent that such additional security is available.

[40 FR 53147, Nov. 14, 1975; 44 FR 69933, Dec. 5, 1979]

§ 36.227 Recordkeeping, reporting and audit.

(a) The standard clauses regarding "Accounts, Audit, and Records" and "Examination of Records" as set forth in 41 CFR 3-4.60 apply to contracts awarded under the Act. Further, Recordkeeping will be in accordance with uniform Administrative Standards.

(b) In addition, where Federal financial assistance is involved in the contract effort, the following clause, which is also set forth in 41 CFR 3-4.60, will be incorporated as a special provision of such contracts:

REPORTS TO THE INDIAN PEOPLE

The contractor, as a recipient of Federal financial assistance, shall make reports and information available to the Indian people served or represented by the contractor. Such reports will reflect how the Federal assistance funds were utilized to the benefit of the Indian people served or represented as follows: (insert specific reporting requirements formats and method of distribution to the Indian people as may be prescribed in the scope of the contract and the Uniform Administrative Standards).

(c) *Annual Reporting.* (1) For each fiscal year during which a tribal organization receives or expends funds pursuant to a contract under this subpart, the tribe which requested the contract must submit a report to the Area Director. The report shall include, but need not be limited to, an accounting of the amounts and purposes for which the contract funds were expended and information on the conduct of the program or services involved. The report shall include any other information requested by the Area Director and shall be submitted as follows:

(i) When the contract is with the governing body of an Indian tribe, the tribe shall submit the report to the Area Director.

(ii) When the contract is with a tribal organization other than the governing body of the tribe, the tribe has the option of having the tribal organization prepare the report and submit it to the tribe for review and approval before the tribe submits it to the Area Director.

(iii) When the contract benefits more than one tribe, the tribal organization shall prepare and submit the report to each of the tribes benefiting under the contract. Each tribe shall endorse the report before submitting it to the Area Director.

(2) The annual report shall be submitted to the Area Director within 60 days of the end of the fiscal year in which the contract was performed. However, the period for submitting the report may be extended if there is just cause for such extension.

(3) In addition to the yearly reporting requirement given in paragraphs (a) and (b) of this section, the tribal contractor shall furnish other reports required by the Secretary.

§ 36.228 Availability of information.

(a) Except as otherwise provided herein and so long as the release of information does not constitute an unwarranted invasion of personal privacy, a tribal contractor under this subpart shall make all reports and information concerning the contract available to the Indian people served or represented by the contractor.

(b) A contractor shall hold confidential all information obtained by personnel under the contract from persons receiving services under the contract related to their examination, care, and treatment, and shall not release such information without the individual's consent except as may be required by law, as may be necessary to provide service to the individual, or as may be necessary to monitor the operations of the program or otherwise protect the Public Health. Information may be disclosed in a form which does not identify particular individuals.

§ 36.229 Penalties.

Section 6 of Pub. L. 93-638, 25 U.S.C. 450(d) provides:

> Whoever, being an officer, director, agent, or employee of, or connected in any capacity with, any recipient of a contract or subcontract pursuant to this Act or the Act of April 16, 1934 (48 Stat. 596), as amended, embezzles, willfully misapplies, steals, or obtains by fraud any of the money, funds, assets, or property which are the subject of such a contract, or subcontract, shall be fined not more than $10,000 or imprisoned for not more than two years, or both, but if the amount so embezzled, willfully misapplied, stolen, or by fraud does not exceed $100, he shall be fined not more than $1,000 or imprisoned not more than one year, or both.

§ 36.230 Contract revisions or amendments.

(a) Any contract made under this subpart may be revised or amended as deemed necessary to carry out the purposes of the program, project, or function being contracted. Those changes initiated by the Government shall be subject to the applicable contract Change Clauses prescribed in 41 CFR 3-4.6013 and 3-4.6014.

(b) However, a tribal contractor may make a written request for a revision or amendment of a contract to the Contracting Officer. Such requests will be treated in the same manner as initial Self-Determination Proposals and evaluated in accordance with the criteria specified in § 36.208 of this subpart. If the contracting officer declines revision or amendment of the contract as requested, he shall notify the tribal organization in writing within 30 days after receiving the request. Thereafter, an appeal to the Contracting Officer's declination to amend the contract will follow the same processing and procedures outlined in § 36.214 of this subpart.

§ 36.231 Retrocession of contract programs.

(a) Whenever an Indian tribe requests retrocession for any contract or portion thereof entered into under this Subpart, retrocession shall be in accordance with the clause titled "Retrocession" as set forth in 41 CFR 3-4.6013 and 3-4.6014, and shall be effective upon a date specified by the Contracting Officer but no later than 120 days after the date of the request from the tribe, except when the tribe and the Contracting Officer mutually agree on a later date.

(b) Immediately after a request for retrocession, representatives of the tribe and the Contracting Officer shall meet and take the following actions:

(1) Mutually agree on a plan for orderly transfer of responsibilities.

(2) Mutually agree on a plan for inventorying materials and supplies on hand.

(3) Establish an accounting of funds, current and anticipated obligations, and costs of operation until the retrocession date.

(4) Identify all records relating to the contract and to the contracted function.

(c) On the date of retrocession, the tribal contractor will deliver to the Contracting Officer all property, materials, supplies and records of whatever nature which have been identified as necessary for the continuation of the program, project or function.

(d) Within 30 calendar days after retrocession, the tribe will furnish the Contracting Officer with a report including but not limited to an accounting of the amounts and purposes for which Federal funds were expended, a description and evaluation of program accomplishments, and reasons why retrocession was requested.

(e) Retrocession of a contract by an Indian tribe shall be without prejudice to:

(1) Any other contract to which it is a party.

(2) Any other contracts it may request.

(3) Any future request to contract for the programs or services covered by the retroceded contract.

(f) Tribal assumption of retroceded contracts. Whenever an Indian tribe chooses to retrocede a contract operated by a tribal organization other than the tribal governing body, the tribal governing body may request to contract for the program. In such a case, the tribal governing body shall submit a contract proposal pursuant to this subpart.

§ 36.232 Contractor assistance.

To the extent practicable, the Director, Indian Health Service, shall, at the request of a tribal organization, provide technical assistance to the contractor in attempting to resolve problems or deficiencies in the performance of the contract and to assist the contractor in taking such corrective action as may be prescribed pursuant to § 36.233(a).

§ 36.233 Assumption and reassumption of contract programs.

(a) When the Director or his delegate determines that the performance of a contractor under these regulations involves (1) the violation of the rights or endangerment of the health, safety, or welfare or any persons, or (2) gross negligence or the mismanagement in the handling or use of funds under the contract, he will, in writing, notify the contractor of such determination and will request that the contractor take such corrective action within such period of time as the Director or his delegate may prescribe.

(b) When the Director or his delegate determines that a contractor has not taken corrective action (as prescribed by him under paragraph (a) of this section) to his satisfaction, he may, after the contractor has been provided an opportunity for a hearing in accordance with paragraph (c) of this section, rescind the contract in whole or in part and, if he deems it appropriate, assume or resume control or operation of the program, activity, or service involved.

(c)(1) When the Director or his delegate has made a determination described in paragraph (b) of this section, he shall in writing notify the contractor of such determination and of the contractor's right to request a review of such determination and of the determination described in paragraph (a) of this section. Such notification by the Director or his delegate shall set forth the reasons for the determination in sufficient detail to enable the contractor to respond and shall inform the contractor of its right to a hearing on the record before a Contract Appeals Board described in paragraph (d) of this section. Upon the request of the contractor for a hearing, the Board, established pursuant to paragraph (d) of this section shall in writing within 10 days of the establishment notify the contractor of the time, place and date of the hearing which will be held not later than 45 days after the request for a hearing.

(2) Where the Director or his delegate determines that a contractor's performance under a contract awarded under this subpart poses an immediate threat to the safety of any person, he may immediately rescind the contract in whole or in part and, if he deems it appropriate, assume or resume control or operation of the program, activity, or service involved. Upon such a decision he will immediately notify the contractor of such action and the basis therefor; and offer the contractor an opportunity for a hearing on the record before the Contract Appeals Board established pursuant to paragraph (d) of this section to be held within 10 days of each action.

(d)(1) The Contract Appeals Board shall be composed of 3 persons appointed by the Director, Indian Health Service. Such persons may not be selected from the immediate office of any person participating in the determinations at issue. The Board shall afford the contractor the right:

(i) To notice of the issues to be considered;

(ii) To be represented by counsel;

(iii) To present witnesses on contractor's behalf;

(iv) To cross-examine other witnesses either orally or through written interrogatories; and

(v) To compel the appearance of Indian Health Service personnel or to take depositions of such persons at reasonable times and places.

(2) The Contracts Appeals Board shall make an initial written decision which shall become final with 20 days unless the Director, Indian Health Service or his representative modifies or reverses the decision. Any such decision by the Director of the Indian Health Service or his representative be in writing, shall be specific as to the reasons for such decision, and shall be considered final.

(3) Where Board is considering issues arising under paragraph (c)(2) of this section, the Board shall within 25 days after the conclusion of the hearing, notify all parties in writing of its decision, which shall be considered final.

(e) In any case where the officer has rescinded a contract under paragraphs (b) or (d) of this section, he may decline to enter into a new contract agreement with the contractor until such time as he is satisfied that the basis for the recission has been corrected.

Nothing in this section shall be construed as contravening the Occupational Safety and Health Act of 1970 (84 Stat. 1590), as amended (29 U.S.C. 651).

§ 36.234 Operation of retroceded or reassumed contracts.

(a) The IHS shall endeavor to provide to the tribe(s) and Indians served by a retroceded or reassumed contract not less than the same quantity and quality of service it would have provided if there had been no contract.

(b) The IHS shall endeavor to provide to the tribe(s) and Indians served by a retroceded or reassumed contract not less than the same quantity and quality of permanent and temporary personnel that meet the U.S. Civil Service qualifications, it would have provided if there has been no contract.

(c) IHS officials cannot decline to accept a retroceded contract or to reassume a contract because they are unable to provide the quality and quantity of service and personnel required in paragraphs (a) and (b) of this section.

§ 36.235 Contract funds.

The tribal organization shall be entitled to be funded for direct and indirect costs at a level which is not less than would have been provided if the IHS had operated the program or portion thereof during the contract period.

§ 36.236 Unexpended funds under contract.

(a) If it becomes apparent during the contract term that the estimated amount of a contract under this subpart will be in excess of actual expenditures under the contract, the identified unexpended funds will be used to provide additional services or benefits within the scope or limitations of the contract.

(b) When both the tribal organization and the IHS agree that it is not practicable to spend all contract funds during the contract term, to the extent authorized by law unexpended funds may be carried over into the succeeding fiscal year contract. Unexpended funds carried over into a succeeding fiscal year shall be added to the contract amount for that fiscal year.

§ 36.237 Contract funding and renegotiation.

The following clause shall be included in contracts awarded under the Act which have a term of more than one year:

CONTRACT FUNDING AND RENEGOTIATION

Funds other than those appropriated during the fiscal year in which the contract commenced, that are included in the contract amount are subject to the availability of appropriations from Congress and there shall be no legal liability on the part of the Government in regard to such funds unless and until they are appropriated. Funds appropriated during the fiscal year in which the contract commenced that are included in the contract amount but not expended at the end of such fiscal year may be carried over and used for contract purposes in the succeeding fiscal year of the contracts operation or, may be used to provide additional services upon modifications of the contract to include such services therein.

Each succeeding year of the contract may be renegotiated prior to the end of the then current fiscal year in order to reflect changes that have taken place beyond the control of the contractor since the contract was originally negotiated or last renegotiated as is applicable.

Subpart J—Indian Health Care Improvement Act Programs

AUTHORITY: Secs. 102, 103, 106, 502, and 704 of Pub. L. 94-437 (25 U.S.C. 1612 and 1613, 25 U.S.C. 1615, 1652, and 1674); sec. 702 of Pub. L. 94-437 (25 U.S.C. 1672); sec. 757, 91 Stat. 392-393 (42 U.S.C. 294y-1).

SOURCE: 42 FR 59646, Nov. 18, 1977, unless otherwise noted.

SUBDIVISION J-1—PROVISIONS OF GENERAL AND SPECIAL APPLICABILITY

§ 36.301 Policy and applicability.

(a) *Policy.* (1) It is the policy of the Secretary to encourage Indians to enter the health professions and to ensure the availability of Indian health professionals to serve Indians. The recruitment and scholarship programs under this subpart will contribute to this objective.

(2) The regulations of this subpart are intended to be consistent with principles of Indian self-determination and to supplement the responsibilities of the Indian Health Sevice for Indian health manpower planning and for assisting Indian tribes and tribal organizations in the development of Indian manpower programs.

(b) *Applicability.* The regulations of this subpart are applicable to the following activities authorized by the Indian Health Care Improvement Act:

(1) The award of health professions recruitment grants under section 102 of the Act to recruit Indians into the health professions (Subdivision J-2);

(2) The award of preparatory scholarship grants under section 103 of the Act to Indians undertaking compensatory preprofessional education (Subdivision J-3);

(3) The award of Indian Health Scholarship grants pursuant to section 225(i)(2) of the Public Health Service Act, as added by section 104 of the Act, to Indian or other students in health professions schools (Subdivision J-4);

(4) The provision of continuing education allowances to health professionals employed by the Service under section 106 of the Act (Subdivision J-5);

(5) Contracts with urban Indian organizations under section 502 of the Act to establish programs in urban areas to make health services more accessible to the urban Indian population (Subdivision J-6); and

(6) Leases with Indian tribes under section 704 of the Act (Subdivision J-7).

§ 36.302 Definitions.

As used in this subpart: (a) "Act" means the Indian Health Care Improvement Act, Pub. L. 94-437 (25 U.S.C. 1601 et seq.).

(b) "Academic year" means the traditional approximately 9 month September to June annual session, except for students who attend summer session in addition to the traditional academic year during a 12 month period, for whom the academic year will be considered to be of approximately 12 months duration.

(c) "Budget period" means the interval of time into which the approved activity is divided for budgetary purposes, as specified in the grant award document.

(d) "Compensatory preprofessional education" means any preprofessional education necessary to compensate for deficiencies in an individual's prior education in order to enable that individual to qualify for enrollment in a health professions school.

(e) "Health or educational entity" means an organization, agency, or combination thereof, which has the provision of health or educational programs as one of its major functions.

(f) "Health professions school" means any of the schools defined in paragraphs (m), (n), or (o) of this section.

(g) "Hospital" means general, tuberculosis, mental, and other types of hospitals, and related facilities such as laboratories, outpatient departments, extended care facilities, facilities related to programs for home health services, self-care units, education or training facilities for health professions personnel operated as an integral part of a hospital, and central services facilities operated in connection with hospitals, but does not include any hospital providing primarily domicillary care.

(h) "Indian" or "Indians" means, for purposes of Subdivisions J-2, J-3, and J-4 of this subpart, any person who is a member of an Indian tribe, as defined in parargraph (i) of this section or any individual who (1), irrespective of whether he or she lives on or near a reservation, is a member of a tribe, band or other organized group terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is the natural child or grandchild of any such member, or (2) is an Eskimo or Aleut or other Alaska Native, or (3) is considered by the Secretary of the Interior to be an Indian for any purpose, or (4) is determined to be an Indian under regulations promulgated by the Secretary.

(i) "Indian health organization" means a nonprofit corporate body composed of Indians which provides for the maximum participation of all interested Indian groups and individuals and which has the provision of health programs as its principal function.

(j) "Indian tribe" means any Indian tribe, band, nation, or other organized group or community, including any Alaska native village or group or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 et seq.), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(k) "Nonprofit" as applied to any private entity means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any private shareholder or individual.

(l) "Project period" means the total time for which support for a project has been approved, as specified in the grant award document.

(m) "School of allied health professions" means a junior college, college, or university—

(1) Which provides, or can provide, programs of education leading to a certificate, or to an associate or baccalaureate degree (or the equivalent or either), or to a higher degree for preparing personnel with responsibilities for supporting, complementing, or supplementing the professional functions of physicians, dentists, and other health professionals in the delivery of health care to patients or assisting environmental engineers and others in environmental health control and preventive medicine activities.

(2) Which, if in a college or univerisity which does not include a teaching hospital or in a junior college, is affiliated through a written agreement with one or more hospitals which provide the hospital component of the clinical training required for completion of such programs of education. The written agreement shall be executed by individuals authorized to act for their respective institutions and to assume on behalf of their institution the obligations imposed by such agreement. The agreement shall provide:

(i) A description of the responsibilities of the school of allied health professions, the responsibilities of the hospital, and their joint responsibilities with respect to the clinical components of such programs of education; and

(ii) A description of the procedure by which the school of allied health professions and the hospital will coordinate the academic and clinical training of students in such programs of education; and

(iii) That, with respect to the clinical component of each such program of education, the teaching plan and resources have been jointly examined and approved by the appropriate faculty of the school of allied health professions and the staff of the hospital.

(3) Which is accredited or assured accreditation by a recognized body or bodies approved for such purpose by the Commissioner of Education of the Department of Health and Human Services.

(n) "School of medicine," "school of dentistry," "school of osteopathy," "school of pharmacy," "school of optometry," school of podiatry," "school of veterinary medicine," and "school of public health" means a school which provides training leading, respectively, to a degree of doctor of medicine, a degree of doctor of dental surgery or an equivalent degree, a degree of doctor of osteopathy, a degree of bachelor of science in pharmacy or an equivalent degree, a degree of doctor of podiatry or an equivalent degree, and graduate degree in public health, and including advanced training related to such training provided by any such school, and is accredited or assured accreditation by a recognized body or bodies approved for such purpose by the Commissioner of Education of the Department of Health and Human Services.

(o) "School of nursing" means a collegiate, associate degree, or diploma school of nursing, as those terms are defined below:

(1) The term "collegiate school of nursing" means a department, division, or other administrative unit in a college or university which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to the degree of bachelor of arts, bachelor of science, bachelor of nursing, or to an equivalent degree, or to a graduate degree in nursing, and including advanced training related to such program of education provided by such school, but only if such program, or such unit, college or university is accredited;

(2) The term "associated degree school of nursing" means a department, division, or other administrative unit in a junior college, community college, college, or university which provides primarily or exclusively a two-year program of education in professional nursing and allied subjects leading to an associate degree in nursing or to an equivalent degree, but only if such program, or such unit, college or university is accredited;

(3) The term "dipoloma school of nursing" means a school affiliated with a hospital or university, or an independent school, which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to a diploma or to equivalent indicia that such program has been satisfactorily completed, but only if such program, or such affiliated school or such hospital or university or such independent school is accredited.

(4) The term "accredited" as used in this subsection when applied to any program of nurse education means a program accredited or assured accreditation by a recognized body or bodies, or by a State agency, approved for such purpose by the Commissioner of Education of the Department of Health and Human Services and when applied to a hospital, school, college, or university (or a unit thereof) means a hospital, school, college, or university (or a unit thereof) which is accredited or assured accreditation by a recognized body or bodies, or by a State agency, approved for such purpose by the Commissioner of Education of the Department of Health and Human Services.

(p) "Secretary" means the Secretary of Health and Human Services and any other Officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(q) "Service" means the Indian Health Service.

(r) "State or local government" means any public health or educational entity which is included within the definition of State or local government in 45 CFR 74.3 and Indian tribes or tribal organizations.

(s) "Tribal organization" means the elected governing body of any Indian tribe or any legally established organization of Indians which is controlled by one or more such bodies or by a board of directors elected or selected by one or more such bodies (or elected by the Indian population to be served by such organization) and which includes the maximum participation of Indians in all phases of its activities.

(t) "Urban center" means any city, with a population of 10,000 or more as determined by the United States Census Bureau, which the Secretary determines has a sufficient urban Indian population with unmet health needs to warrant assistance under Title V of the Act.

(u) "Urban Indian" means any individual who resides in an urban center, as defined in paragraph(s) of this section, and who meets one or more of the four criteria in paragraph (h) (1) through (4) of this section.

(v) "Urban Indian organization" means a nonprofit corporate body situated in an urban center which:

(1) Is composed of urban Indians;

(2) Has the provision of health programs as:

(i) Its principal function, or

(ii) One of its major functions and such health progams are administered by a distinct organizational unit within the organization.

(3) Is governed by a board of directors composed of urban Indians elected or appointed in accordance with the articles of incorporation and bylaws of the organization;

(4) Provides for the maximum participation of all interested Indian groups and individuals; and

(5) Is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in § 36.350(a) of Subdivision J-6 of this subpart. Except, that criteria (2) and (3) of this subsection shall not apply to an organization administering an urban Indian health project under a contract with the Secretary prior to October 1, 1977, for the period of such contract or until July 1, 1978, whichever is later.

§ 36.303 Indians applying for scholarships.

(a) For purposes of scholarship grants under Subdivisions J-3 and J-4 of this subpart, Indian applicants must submit evidence of their tribal membership (or other evidence that that applicant is an Indian as defined in paragraph (h) of § 36.302 of this subdivision) satisfactory to the Secretary.

(b) Where an applicant is a member of a tribe recognized by the Secretary of the Interior, the applicant must submit evidence of his or her tribal membership, such as:

(1) Certification of tribal enrollment by the Secretary of the Interior acting through the Bureau of Indian Affairs (BIA); or

(2) In the absence of such BIA certification, documentation that the applicant meets the requirements of tribal membership as prescribed by the charter, articles of incorporation or other legal instrument of the tribe and has been officially designated a tribal member by an authorized tribal official; or

(3) Other evidence of tribal membership satisfactory to the Secretary.

(c) Where the applicant is a member of a tribe terminated since 1940 or a State recognized tribe, the applicant must submit documentation that the applicant meets the requirements of tribal membership as prescribed by the charter, articles of incorporation or other legal instrument of the tribe and has been officially designated a tribal member by an authorized tribal official; or other evidence, satisfactory to the Secretary, that the applicant is a member of the tribe. In addition, if the terminated or State recognized tribe of which the applicant is a member is not on a list of such tribes published by the Secretary in the FEDERAL REGISTER. the applicant must submit documentation as may be required by the Secretary that the tribe is a tribe terminated since 1940 or is recognized by the State in which the tribe is located in accordance with the law of that State.

(d) An applicant who is not a tribal member, but who is a natural child or grandchild of a tribal member as defined in paragraph (h) of § 36.302 of this subdivision must submit evidence of such fact which is satisfactory to the Secretary, in addition to evidence of his or her parent's or grandparent's tribal membership in accordance with paragraphs (b) and (c) of this section.

§ 36.304 Publication of a list of allied health professions.

The Secretary, acting through the Service, shall publish from time to time in the FEDERAL REGISTER a list of the allied health professions for consideration for the award of preparatory and Indian Health scholarships under subdivisions J-3 and J-4 of this Subpart, based upon his determination of the relative needs of Indians for additional service in specific allied health professions. In making that determination, the needs of the Service will be given priority consideration.

§ 36.305 Additional conditions.

The Secretary may, with respect to any grant award under this subpart, impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

NOTE: *Nondiscrimination.* (a) Grants and contracts under this subpart are exempted from the requirements of section 601 of the Civil Rights Act of 1964 (42 U.S.C. 2000d), prohibiting discrimination on the basis of race, color or national origin, by regulation at 45 CFR 80.3(d) which provides, with respect to Indian Health Services, that "An individual shall not be deemed subjected to discrimination by reason of his exclusion from the benefits of a program limited by Federal law to individuals of a particular race, color, or national origin different from his."

(b) Attention is called to the requirements of Title IX of the Education Amendments of 1972 and in particular to section 901 of such Act which provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benifits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.

(c) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

SUBDIVISION J-2—HEALTH PROFESSIONS RECRUITMENT PROGRAM FOR INDIANS

§ 36.310 Health professions recruitment grants.

Grants awarded under this subdivision, in accordance with section 102 of the Act, are for the purpose of assisting in meeting the costs of projects to:

(a) Identify Indians with a potential for education or training in the health professions and encouraging and assisting them (1) To enroll in schools of medicine, osteopathy, dentistry, veterinary medicine, optometry, podiatry, pharmacy, public health, nursing, or allied health professions; or (2), if they are not qualified to enroll in any such school, to undertake such post-secondary education or training as may be required to qualify them for enrollment;

(b) Publicize existing sources of financial aid available to Indians enrolled in any school referred to in paragraph (a)(1) of this section or who are undertaking training necessary to qualify them to enroll in any such school; or

(c) Establish other programs which the Secretary determines will enhance and facilitate the enrollment of Indians, and the subsequent pursuit and completion by them of courses of study, in any school referred to in paragraph (a)(1) of this section.

§ 36.311 Eligibility.

Any Indian tribe, tribal organization, urban Indian organization, Indian health organization or any public or other nonprofit private health or educational entity is eligible to apply for a health professions recruitment grant under this subdivision.

§ 36.312 Application.

(a) An application for a health professions recruitment grant under this subdivision shall be submitted to the Secretary at such time and in such form and manner as the Secretary acting through the Service may prescribe.[1]

(b) The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations of this subdivision.

(c) In addition to such other pertinent information as the Secretary may require, the application for a health professions recruitment grant shall contain the following:

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[1] Applications and instructions may be obtained from the appropriate Indian Health Service Area or Program Office or by writing the Director, Indian Health Service, Room 5A-55, 5600 Fishers Lane, Rockville, Maryland 20857.

(1) A description of the legal status and organization of the applicant;

(2) A description of the current and proposed participation of Indians (if any) in the applicant's organization.

(3) A description of the target Indian population to be served by the proposed project and the relationship of the applicant to that population;

(4) A narrative description of the nature, duration, purpose, need for and scope of the proposed project and of the manner in which the applicant intends to conduct the project including:

(i) Specific measurable objectives for the proposed project;

(ii) How the described objectives are consistent with the purposes of section 102 of the Act;

(iii) The work and time schedules which will be used to accomplish each of the objectives;

(iv) A description of the administrative, managerial, and organizational arrangements and the facilities and resources to be utilized to conduct the proposed project;

(v) The name and qualifications of the project director or other individual responsible for the conduct of the project; the qualifications of the prinicipal staff carrying out the project; and a description of the manner in which the applicant's staff is or will be organized and supervised to carry out the proposed project;

(5) An itemized budget for the entire project period for which support is sought and justification of the amount of grant funds requested;

(6) The intended financial participation, if any, of the applicant in the proposed project specifying the type of contributions such as cash or services, loans of full or part-time staff, equipment, space, materials or facilities or other contributions;

(7) When the target population of a proposed project includes a particular Indian tribe or tribes, an official document in such form as is prescribed by the tribal governing body of each such tribe indicating that the tribe or tribes will cooperate with the applicant.

(d) In the case of proposed projects for identification of Indians with a potential for education or training in the health professions, applications must include a method of assessing the potential of interested Indians for undertaking necessary education or training in the health professions. Proposed projects may include, but are not limited to, the following activities:

(1) Identifying Indian elementary and secondary school students through observations, aptitude or other testing, academic performance, performance in special projects and activities, and other methods as may be designed or developed;

(2) Identifying Indians in college or university programs, related employment, upward mobility programs or other areas of activity indicative of interest and potential;

(3) Review of the upward mobility plans, skills, banks etc. of organizations employing Indians to identify individuals with appropriate career orientations, expression of interest, or recognized potential;

(4) Conducting workshops, health career days, orientation projects or other activities to identify interested Indians at any age level;

(5) Performing liaison activities with Indian professional organizations, Indian education programs (including adult education), Indian school boards, Indian parent, youth recreation or community groups, or other Indian special interest or activity groups;

(6) Identifying those Indians with an interest and potential who cannot undertake compensatory education or training in the health professions because of financial need.

(e) Proposed projects designed to encourage and assist Indians to enroll in health professions schools; or, if not qualified to enroll, to undertake post-secondary education or training required to qualify them for enrollment may include, but are not limited to, the following activities:

(1) Providing technical assistance and counseling to encourage and assist Indians identified as having a potential for education or training in the health professions—

(i) To enroll in health professions schools.

(ii) To undertake any post-secondary education and training required to qualify them to enroll in health professions schools, and

(iii) To obtain financial aid to enable them to enroll in health professions schools or undertake post-secondary education or training required to qualify them to enroll in such schools;

(2) Conducting programs to (i) identify factors such as deficiencies in basic communication, research, academic subject matter (such as science, mathematics, etc.), or other skills which may prevent or discourage Indians from enrolling in health professions schools or undertaking the post-secondary education or training required to qualify them to enroll, and (ii) provide counseling and technical assistance to Indians to assist them in undertaking the necessary education, training or other activities to overcome such factors.

(f) Proposed projects to publicize existing kinds of financial aid available to Indians enrolled in health professions schools or to Indians undertaking training necessary to qualify them to enroll in such schools may include, but are not limited to, the following activities:

(1) Collecting information on available sources of financial aid and disseminating such information to Indian students, Indians, recruited under programs assisted by grants under this subdivision and to Indian tribes, tribal organizations, urban Indian organizations, Indian health organizations and other interested groups and communities throughout the United States;

(2) Providing information on available sources of financial aid which can be utilized by programs and counselors assisting Indians to obtain financial aid.

(g) Proposed projects for establishment of other programs which will enhance or facilitate enrollment of Indians in health professions schools and the subsequent pursuit and completion by them of courses of study in such schools may include, but are not limited to, the following activities:

(1) Compilation and dissemination of information on—

(i) Health professions education or training programs and the requirements for enrollment in such programs; and

(ii) Post-secondary education or training curricula and programs designed to qualify persons for enrollment in health professions schools;

(2) Developing and coordinating career orientation programs in local schools (including high schools) and colleges and universites;

(3) Developing programs to enable Indians to gain exposure to the health professions such as arranging for (i) visits to health care facilities and programs and meetings or seminars with health professionals, (ii) part-time summer or rotating employment in health care facilities, programs, or offices of health professionals, (iii) volunteer programs, or (iv) other means of providing such exposure;

(4) Developing programs which relate tribal culture and tradition, including native medicine, to careers in the health professions; and

(5) Developing programs to make Indians aware of projected health manpower needs, expected employment opportunities in the health professions, and other factors in order to orient and motivate Indians to pursue careers in the health professions.

§ 36.313 Evaluation and grant awards.

(a) Within the limits of funds available for such purpose, the Secretary, acting through the Service, may award health professions recruitment grants to those eligible applicants whose proposed projects will in his judgment best promote the purposes of section 102 of the Act, taking into consideration:

(1) The potential effectiveness of the proposed project in carrying out such purposes;

(2) The capability of the applicant to successfully conduct the project;

(3) The accessibility of the applicant to target Indian communities or tribes, including evidence of past or potential cooperation between the applicant and such communities or tribes;

(4) The relationship of project objectives to known or anticipated Indian health manpower deficiencies;

(5) The soundness of the fiscal plan for assuring effective utilization of grant funds;

(6) The completeness of the application.

(b) Preference shall be given to applicants in the following order or priority: (1) Indian tribes, (2) tribal organizations, (3) urban Indian organizations and other Indian health organizations, and (4) public and other nonprofit profit private health or educational entities.

(c) The amount of any award under this subdivision will be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of the direct costs of the project plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of his estimate of the actual indirect costs reasonably related to the project, or

(2) on the basis of a percentage of all or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect cost. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(d) All grant awards shall be in writing, and shall set forth the amount of funds granted and the period for which support is provided.

(e) Neither the approval of any project nor the award of any grant shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application at such times and in such form as the Secretary may dictate.

§ 36.314 Payment and use of funds.

(a) The Secretary acting through the Service will make payments to a grantee either by way of reimbursement for expenses incurred in the project period, or in advance for expenses to be incurred, to the extent he determines such payments are necessary to promptly initiate and conduct the approved project.

(b) Any funds granted under this subdivision shall be used solely for carrying out the approved project in accordance with section 102 of the Act, the regulations of this subdivision, and the terms and conditions of the grant award.

§ 36.315 Publication of list of grantees and projects.

The Secretary acting through the Service shall publish annually in the FEDERAL REGISTER a list of organizations receiving grants under this subdivision including for each grantee:

(a) The organization's name and address;

(b) The amount of the grant;

(c) A summary of the project's purposes and its geographic location.

§ 36.316 Alteration or renovation.

Grant funds used for alteration or renovation shall be subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, 30 FR 12319 (Sept. 24, 1965), as amended, and with applicable rules, regulations, and procedures prescribed under that Order.

§ 36.317 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart except that when the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total or selected elements of the reimbursable direct costs incurred.

(b) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of (i) any amount not accounted for pursuant to paragraph (a) of this section; and (ii) any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74. Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successor or assigns by set-off or other action as provided by law.

§ 36.318 Publications and copyright.

(a) *State and local governments.* Where the grantee is a State or local government the Department of Health and Human Services copyright requirement set forth in 45 CFR 74.140 shall apply with respect to any book or other copyrightable materials developed or resulting from a project supported by a grant under this subpart.

(b) *Grantees other than State and local governments.* Where the grantee is not a State or local government, except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from a project supported by a grant under this subpart, subject to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate and dispose of such materials, and to authorize others to do so.

§ 36.319 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles shall apply to all grants under this subpart to State and local governments. The relevant provisions of the following subparts of Part 74 shall also apply to all other grantee organizations under this subdivision:

SUBPART

A—General.
B—Cash Depositories.
C—Bonding and Insurance.
D—Retention and Custodial Requirements for Records.
F—Grant-Related Income.
K—Grant Payment Requirements.
L—Budget Revision Procedures.
M—Grant Closeout, Suspension, and Termination.
O—Property.
Q—Cost Principles.

SUBDIVISION J-3—HEALTH PROFESSIONS PREPARATORY SCHOLARSHIP PROGRAM FOR INDIANS

§ 36.320 Preparatory scholarship grants.

Scholarship grants may be awarded under this subdivision and section 103 of the act for the period (not to exceed two academic years) necessary to complete a recipient's compensatory preprofessional education to enable the recipient to qualify for enrollment or re-enrollment in a health professions school. Examples of individuals eligible for such grants are the individual who:

(a) Has completed high school equivalency and needs compensatory preprofessional education to enroll in a health professions school;

(b) Has a baccalaureate degree and needs compensatory preprofessional education to qualify for enrollment in a health professions school; or

(c) Has been enrolled in a health professions school but is no longer so enrolled and needs preprofessional education to qualify for readmission to a health professions school.

§ 36.321 Eligibility.

To be eligible for a preparatory scholarship grant under this subdivision an applicant must:

(a) Be an Indian;

(b) Have successfully completed high school education or high school equivalency;

(c) Have demonstrated to the satisfaction of the Secretary the desire and capability to successfully complete courses of study in a health professions school;

(d) Be accepted for enrollment in or be enrolled in any compensatory preprofessional education course or curriculum meeting the criteria in § 36.320 of this subdivision; and

(e) Be a citizen of the United States.

§ 36.322 Application and selection.

(a) An application for a preparatory scholarship grant under this subdivision shall be submitted in such form and at such time as the Secretary acting through the Service may prescribe.[3] However, an application must indicate:

(1) The health profession which the applicant wishes to enter, and

(2) Whether the applicant intends to provide health services to Indians upon completion of health professions education or training by serving as described in § 36.333 or otherwise as indicated on the application.

(b) Within the limits of funds available for the purpose, the Secretary, acting through the Service, shall make scholarship grant awards for a period not to exceed two academic years of an individual's compensatory preprofessional education to eligible applicants taking into consideration:

(1) Academic performance;

(2) Work experience;

(3) Faculty recommendations;

(4) Stated reasons for asking for the scholarship; and

(5) The relative needs of the Service and Indian health organizations for persons in specific health professions.

§ 36.323 Scholarship and tuition.

(a) Scholarship grant awards under this subdivision shall consist of:

(1) A stipend of $400 per month adjusted in accordance with paragraph (c) of this section; and

(2) An amount determined by the Secretary for transportation, tuition, fees, books, laboratory expenses, and other necessary educational expenses.

(b) The portion of the scholarship for the costs of tuition and fees as indicated in the grant award will be paid directly to the school upon receipt of an invoice from the school. The stipend and remainder of the scholarship grant award will be paid monthly to the grantee under the conditions specified in the grant award.

(c) The amount of the monthly stipend specified in paragraph (a)(1) of this section shall be increased by the Secretary for each academic year ending in a fiscal year beginning after September 30, 1978, by an amount (rounded to the next highest multiple of $1) equal to the amount of such stipend multiplied by the overall percentage (as set forth in the report transmitted to the Congress under section 5303 of Title 5, United States Code) of the adjustment (if such adjustment is an increase) in the rates of pay under the General Schedule made effective in the fiscal year in which such academic year ends.

§ 36.324 Publication of a list of recipients.

The Secretary, acting through the Service, will publish annually in the FEDERAL REGISTER a list of recipients of scholarship grants under this subdivision, including the name of each recipient, tribal affiliation and school.

SUBDIVISION J-4—INDIAN HEALTH SCHOLARSHIP PROGRAM

§ 36.330 Indian health scholarships.

Indian Health Scholarships will be awarded by the Secretary pursuant to Subpart IV of Part C of Title VII of the Public Health Service Act, and such implementing regulations as may be promulgated by the Secretary except as set out in this subdivision for the purpose of providing scholarships to Indian and other students at health professions schools in order to obtain health professionals to serve Indians.

§ 36.331 Selection.

(a) The Secretary, acting through the Service, shall determine the individuals who receive Indian Health Scholarships.

(b) Priority shall be given to applicants who are Indians.

§ 36.332 Service obligation.

The service obligation provided in Section 757(b)(2) of the Public Health

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[3] Applications and instructions may be obtained from the appropriate Indian Health Service Area or Program Office.

Service Act shall be met by the recipient of an Indian Health Scholarship by service in:

(a) The Indian Health Service.

(b) An urban Indian organization assisted under Subdivision J-6.

(c) In private practice of his or her profession if, the practice (1) is situated in a health manpower shortage area, designated under section 332 of the Public Health Service Act and (2) addresses the health care needs of a substantial number of Indians as determined by the Secretary in accordance with guidelines of the Service.

§ 36.333 Distribution of scholarships.

The Secretary, acting through the Service, shall determine the distribution of Indian Health Scholarships among the health professions based upon the relative needs of Indians for additional service in specific health professions. In making that determination the needs of the Service will be given priority consideration. The following factors will also be considered:

(a) The professional goals of recipients of scholarships under section 103 of the Indian Health Care Improvement Act; and

(b) The professional areas of study of Indian applicants.

§ 36.334 Publication of a list of recipients.

The Secretary, acting through the Service, will publish annually in the FEDERAL REGISTER a list of recipients of Indian Health Scholarships, including the name of each recipient, tribal affiliation if applicable, and school.

SUBDIVISION J-5—CONTINUING EDUCATION ALLOWANCES

§ 36.340 Provision of continuing education allowances.

In order to encourage physicians, dentists and other health professionals to join or continue in the Service and to provide their services in the rural and remote areas where a significant portion of the Indian people reside, the Secretary, acting through the Service, may provide allowances to health professionals, employed in the Service in order to enable them to leave their duty stations for not to exceed 480 hours of professional consultation and refresher training courses in any one year.

SUBDIVISION J-6—CONTRACTS WITH URBAN INDIAN ORGANIZATIONS

§ 36.350 Contracts with Urban Indian organizations.

(a) The Secretary, acting through the Service, to the extent that funds are available for the purpose, shall contract with urban Indian organizations selected under § 36.351 of this subdivision to carry out the following activities in the urban centers where such organizations are situated:

(1) Determine the population of urban Indians which are or could be recipients of health referral or care services;

(2) Identify all public and private health service resources within the urban center in which the organization is situated which are or may be available to urban Indians;

(3) Assist such resources in providing service to such urban Indians;

(4) Assist such urban Indians in becoming familiar with and utilizing such resources;

(5) Provide basic health education to such urban Indians;

(6) Establish and implement manpower training programs to accomplish the referral and education tasks set forth in paragraphs (a)(3) through (5) of this section;

(7) Identify gaps between unmet health needs of urban Indians and the resources available to meet such needs;

(8) Make recommendations to the Secretary and Federal, State, local, and other resource agencies on methods of improving health service programs to meet the needs of urban Indians; and

(9) Prove or contract for health care services to urban Indians where local health delivery resources are not available, not accessible, or not acceptable to the urban Indians to be served.

(b) Contracts with urban Indian organizations pursuant to this title shall be in accordance with all Federal contracting laws and regulations except that, in the discretion of the Secretary, such contracts may be negotiated without advertising and need not conform to the provisions of the Act of August 24, 1935 as amended, (The Miller Act, 40 U.S.C. 270a et seq. which is concerned with bonding requirements).

(c) Payments under contracts may be made in advance or by way of reimbursement and in such installments and on such conditions as the Secretary deems necessary to carry out the purposes of Title V of the Act.

(d) Notwithstanding any provision of law to the contrary, the Secretary may, at the request or consent of an urban Indian organization, revise or amend any contract made by him with such organization pursuant to this subdivision as necessary to carry out the purposes of Title V of this Act: Provided, however, that whenever an urban Indian organization requests retrocession of the Secretary for any such contract, retrocession shall become effective upon a date specified by the Secretary not more than one hundred and twenty days from the date of the request by the organization or at such later date as may be mutually agreed to by the Secretary and the organization.

(e) In connection with any contract made pursuant to this subdivision, the Secretary may permit an urban Indian organization to utilize, in carrying out such contract, existing facilities owned by the Federal Government within his jurisdiction under such terms and conditions as may be agreed upon for their use and maintenance.

§ 36.351 Application and selection.

(a) Proposals for contracts under this subdivision shall be submitted in such form and manner and at such time as the Secretary acting through the Service may prescribe.

(b) The Secretary, acting through the Service shall select urban Indian organizations with which to contract under this subdivision whose proposals will in his judgment best promote the purposes of Title V of the Act taking into consideration the following factors:

(1) The extent of the unmet health care needs of the urban Indians in the urban center involved determined on the basis of the latest available statistics on disease incidence and prevalence, life expectancy, infant mortality, dental needs, housing conditions, family income, unemployment statistics, etc.

(2) The urban Indian population which is to receive assistance in the following order of priority:

(i) 9,000 or more;

(ii) 4,500 to 9,000;

(iii) 3,000 to 4,500;

(iv) 1,000 to 3,000;

(v) under 1,000.

(3) The relative accessibility which the urban Indian population to be served has to health care services, in the urban center. Factors to be considered in determining relative accessibility include:

(i) Cultural barriers;

(ii) Discrimination against Indians;

(iii) Inability to pay for health care;

(iv) Lack of facilities which provide free care to indigent persons;

(v) Lack of state or local health programs;

(vi) Technical barriers created by State and local health agencies;

(vii) Availability of transportation to health care services;

(viii) Distance between Indian residences and the nearest health care facility.

(4) The extent to which required activities under § 36.350(a) of this subdivision would duplicate any previous or current public or private health services projects in the urban center funded by another source. Factors to be considered in determining duplication include:

(i) Urban Indian utilization of existing health services funded by other sources;

(ii) Urban Indian utilization of existing health services delivered by an urban Indian organization funded by other sources.

(5) The appropriateness and likely effectiveness of the activities required in § 36.350(a) of this subdivision in the urban center involved.

(6) The capability of the applicant urban Indian organization to perform satisfactorily the activities required in § 36.350(a) of this subdivision and to contract with the Secretary.

(7) The extent of existing or likely future participation in the activities required in § 36.350(a) of this subdivi-

sion by appropriate health and health related Fedeal, State, local, and other resource agencies.

(8) Whether the city has an existing urban Indian health program.

(9) The applicant organization's record of performance, if any, in regard to any of the activities required in § 36.350(a) of this subdivision.

(10) Letters demonstrating local support for the applicant organization from both the Indian and non-Indian communities in the urban center involved.

[42 FR 59646, Nov. 18, 1977; 42 FR 61861, Dec. 7, 1977]

§ 36.352 Fair and uniform provision of services.

Contracts with urban Indian organizations under this subdivision shall incorporate the following clause:

The Contractor agrees, consistent with medical need, and the efficient provision of medical services to make no discriminatory distinctions against Indian patients or beneficiaries of this contract which are inconsistent with the fair and uniform provision of services.

§ 36.353 Reports and records.

For each fiscal year during which an urban Indian organization receives or expends funds pursuant to a contract under this title, such organization shall submit to the Secretary a report including information gathered pursuant to § 36.350(a) (7) and (8) of this subdivision, information on activities conducted by the organization pursuant to the contract, an accounting of the amounts and purposes for which Federal funds were expended, and such other information as the Secretary may request. The reports and records of the urban Indian organization with respect to such contract shall be subject to audit by the Secretary and the Comptroller General of the United States.

SUBDIVISION J-7—LEASES WITH INDIAN TRIBES

§ 36.360 Leases with Indian tribes.

(a) Any land or facilities otherwise authorized to be acquired, constructed, or leased to carry out the purposes of the Act may be leased or subleased from Indian tribes for periods not in excess of twenty years.

(b) Leases entered into pursuant to paragraph (a) shall be subject to the requirements of section 322 of the Economy Act (40 U.S.C. 278a), which limits expenditures for rent and alterations, improvements and repairs on leased buildings.

PART 37—SPECIFICATIONS FOR MEDICAL EXAMINATIONS OF UNDERGROUND COAL MINERS

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AUTHORITY: Sec. 203, 83 Stat. 763; 30 U.S.C. 843.

SOURCE: 43 FR 33715, Aug. 1, 1978, unless otherwise noted.

Subpart—Chest Roentgenographic Examinations

§ 37.1 Scope.

The provisions of this subpart set forth the specifications for giving, interpreting, classifying, and submitting chest roentgenograms required by section 203 of the act to be given to underground coal miners and new miners.

§ 37.2 Definitions.

Any term defined in the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the act. As used in this subpart:

(a) "Act" means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801, et seq.).

(b) "ALOSH" means the Appalachian Laboratory for Occupational Safety and Health, Box 4258, Morgantown, W. Va. 26505. Although the Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, has programmatic responsibility for the chest roentgenographic examination program, the Institute's facility in Morgantown—ALOSH—is used throughout this subpart in referring to the administration of the program.

(c) "Chest roentgenogram" means a single posteroanterior roentgenographic projection or radiograph of the chest at full inspiration recorded on roentgenographic film.

(d) "Convenient time and place" with respect to the conduct of any examination under this subpart means that the examination must be given at a reasonable hour in the locality in which the miner resides or a location that is equally accessible to the miner. For example, examinations at the mine during, immediately preceding, or immediately following work and a "no appointment" examination at a medical facility in a community easily accessible to the residences of a majority of the miners working at the mine, shall be considered of equivalent convenience for purposes of this paragraph.

(e) "Institute" and "NIOSH" mean the National Institute for Occupational Safety and Health Center for Disease Control, Public Health Service, Department of Health and Human Services.

(f) "ILO-U/C 1971 International Classification of Radiographs of Pneumoconioses" or "ILO-U/C Classification" means the classification of the pneumoconioses devised in 1971 by an international committee of the International Labour Office and described in "Medical Radiography and Photography," volume 48, No. 3, December 1972.

(g) "Miner" means any individual including any coal mine construction worker who is working in or at any underground coal mine, but does not include any surface worker who does not have direct contact with underground coal mining or with coal processing operations.

(h) "Operator" means any owner, lessee, or other person who operates, controls, or supervises an underground coal mine or any independent contractor performing services or construction at such mine.

(i) "Panel of 'B' Readers" means the U.S. Public Health Service Consultant Panel of "B" Readers, c/o ALOSH, P.O. Box 4258, Morgantown, W. Va. 26505.

(j) "Preemployment physical examination" means any medical examination which includes a chest roentgenographic examination given in accordance with the specifications of this subpart to a person not previously employed by the same operator or at the same mine for which that person is being considered for employment.

(k) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human

Services to whom the authority involved may be delegated.

(l) "MSHA" means the Mine Safety and Health Administration, Department of Labor.

§ 37.3 Chest roentgenograms required for miners.

(a) *Voluntary examinations.* Every operator shall provide to each miner who is employed in or at any of its underground coal mines and who was employed in underground coal mining prior to December 30, 1969, or who has completed the required examinations under § 37.3(b) an opportunity for a chest roentgenogram in accordance with this subpart:

(1) Following August 1, 1978 ALOSH will notify the operator of each underground coal mine of a period within which the operator may provide examinations to each miner employed at its coal mine. The period shall begin no sooner than the effective date of these regulations and end no later than a date specified by ALOSH separately for each coal mine. The termination date of the period will be approximately 5 years from the date of the first examination which was made on a miner employed by the operator in its coal mine under the former regulations of this subpart adopted July 27, 1973. Within the period specified by ALOSH for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under § 37.5.

EXAMPLE: ALOSH finds that between July 27, 1973, and March 31, 1975, the first roentgenogram for a miner who was employed at mine Y and who was employed in underground coal mining prior to December 30, 1969, was made on January 1, 1974. ALOSH will notify the operator of mine Y that the operator may select and designate on its plan a 6-month period within which to offer its examinations to its miners employed at mine Y. The 6-month period shall be scheduled between August 1, 1978 and January 1, 1979 (5 years after January 1, 1974).

(2) For all future voluntary examinations, ALOSH will notify the operator of each underground coal mine when sufficient time has elapsed since the end of the previous 6-month period of examinations. ALOSH will specify to the operator of each mine a period within which the operator may provide examinations to its miners employed at its coal mine. The period shall begin no sooner than 3½ years and end no later than 4½ years subsequent to the ending date of the previous 6-month period specified for a coal mine either by the operator on an approved plan or by ALOSH if the operator did not submit an approved plan. Within the period specified by ALOSH for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under § 37.5.

EXAMPLE: ALOSH finds that examinations were previously provided to miners employed at mine Y in a 6-month period from July 1, 1979, to December 31, 1979. ALOSH notifies the operator at least 3 months before July 1, 1983 (3½ years after December 31, 1979) that the operator may select and designate on its plan the next 6-month period within which to offer examinations to its miners employed at mine Y. The 6-month period shall be scheduled between July 1, 1983, and July 1, 1984 (between 3½ and 4½ years after December 31, 1979).

(3) Within either the next or future period(s) specified by ALOSH to the operator for each of its coal mines, the operator of the coal mine may select a different 6-month period for each of its mines within which to offer examinations. In the event the operator does not submit an approved plan, ALOSH will specify a 6-month period to the operator within which miners shall have the opportunity for examinations.

(b) *Mandatory examinations.* Every operator shall provide to each miner who begins working in or at a coal mine for the first time after December 30, 1969:

(1) An initial chest roentgenogram as soon as possible, but in no event later than 6 months after commencement of employment. A preemployment physical examination which was made within the 6 months prior to the date on which the miner started to work will be considered as fulfilling this requirement. An initial chest roentgenogram given to a miner according to former regulations for this subpart prior to August 1, 1978 will also be considered as fulfilling this requirement.

(2) A second chest roentgenogram, in accordance with this subpart, 3 years following the initial examination if the miner is still engaged in underground coal mining. A second roentgenogram given to a miner according to former regulations under this subpart prior to August 1, 1978 will be considered as fulfilling this requirement.

(3) A third chest roentgenogram 2 years following the second chest roentgenogram if the miner is still engaged in underground coal mining and if the second roentgenogram shows evidence of category 1, category 2, category 3 simple pheumoconiosis, or complicated pheumoconiosis (ILO-U/C classification).

(c) ALOSH will notify the miner when he or she is due to receive the second or third mandatory examination under (b) of this section. Similarly, ALOSH will notify the coal mine operator when the miner is to be given a second examination. The operator will be notified concerning a miner's third examination only with the miner's written consent, and the notice to the operator shall not state the medical reason for the examination nor that it is the third examination in the series. If the miner is notified by ALOSH that the third mandatory examination is due and the operator is not so notified, availability of the roentgenographic examination under the operator's plan shall constitute the operator's compliance with the requirement to provide a third mandatory examination even if the miner refuses to take the examination.

(d) The opportunity for chest roentgenograms to be available by an operator for purposes of this subpart shall be provided in accordance with a plan which has been submitted and approved in accordance with this subpart.

(e) Any examinations conducted by the Secretary in the National Study of Coal Workers' Pneumoconiosis after January 1, 1977, but before August 1, 1978 shall satisfy the requirements of this section with respect to the specific examination given (see § 37.6(d)).

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978]

§ 37.4 Plans for chest roentgenographic examinations.

(a) Every plan for chest roentgenographic examinations of miners shall be submitted on forms prescribed by the Secretary to ALOSH within 120 calendar days after August 1, 1978. In the case of a person who after August 1, 1978, becomes an operator of a mine for which no plan has been approved, that person shall submit a plan within 60 days after such event occurs. A separate plan shall be submitted by the operator and by each construction contractor for each underground coal mine which has a MSHA identification number. The plan shall include:

(1) The name, address, and telephone number of the operator(s) submitting the plan;

(2) The name, MSHA identification number for respirable dust measurements, and address of the mine included in the plan;

(3) The proposed beginning and ending date of the 6-month period for voluntary examinations (see § 37.3(a)) and the estimated number of miners to be given or offered examinations during the 6-month period under the plan;

(4) The name and location of the approved X-ray facility or facilities, and the approximate date(s) and time(s) of day during which the roentgenograms will be given to miners to enable a determination of whether the examinations will be conducted at a convenient time and place;

(5) If a mobile facility is proposed, the plan shall provide that each miner be given adequate notice of the opportunity to have the examination and that no miner shall have to wait for an examination more than 1 hour before or after his or her work shift. In addition, the plan shall include:

(i) The number of change houses at the mine.

(ii) One or more alternate nonmobile approved facilities for the reexamination of miners and for the mandatory examination of miners when necessary (see § 37.3(b)), or an assurance that the mobile facility will return to the location(s) specified in the plan as frequently as necessary to provide for examinations in accordance with these regulations.

(iii) The name and location of each change house at which examinations will be given. For mines with more than one change house, the examinations shall be given at each change house or at a change house located at a convenient place for each miner.

(6) The name and address of the "A" or "B" reader who will interpret and classify the chest roentgenograms.

(7) Assurances that: (i) The operator will not solicit a physician's roentgenographic or other findings concerning any miner employed by the operator,

(ii) Instructions have been given to the person(s) giving the examinations that duplicate roentgenograms or copies of roentgenograms will not be made and that (except as may be necessary for the purpose of this subpart) the physician's roentgenographic and other findings, as well as the occupational history information obtained from a miner unless obtained prior to employment in a preemployment examination, and disclosed prior to employment, will not be disclosed in a manner which will permit identification of the employee with the information about him, and

(iii) The roentgenographic examinations will be made at no charge to the miner.

(b) Operators may provide for alternate facilities and "A" or "B" readers in plans submitted for approval.

(c) The change of operators of any mine operating under a plan approved pursuant to § 37.5 shall not affect the plan of the operator which has transferred responsibility for the mine. Every plan shall be subject to revision in accordance with paragraph (d) of this section.

(d) The operator shall advise ALOSH of any change in its plan. Each change in an approved plan is subject to the same review and approval as the originally approved plan.

(e) The operator shall promptly display in a visible location on the bulletin board at the mine its proposed plan or proposed change in plan when it is submitted to ALOSH. The proposed plan or change in plan shall remain posted in a visible location on the bulletin board until ALOSH either grants or denies approval of it at which time the approved plan or denial of approval shall be permanently posted. In the case of an operator who is a construction contractor and who does not have a bulletin board, the construction contractor must otherwise notify its employees of the examination arrangements. Upon request, the contractor must show ALOSH written evidence that its employees have been notified.

(f) Upon notification from ALOSH that sufficient time has elapsed since the previous period of examinations, the operator will resubmit its plan for each of its coal mines to ALOSH for approval for the next period of examinations (see § 37.3(a)(2)). The plan shall include the proposed beginning and ending dates of the next period of examinations and all information required by paragraph (a) of this section.

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978]

§ 37.5 Approval of plans.

(a) Approval of plans granted prior to August 1, 1978 is no longer effective.

(b) If, after review of any plan submitted pursuant to this subpart, the Secretary determines that the action to be taken under the plan by the operator meets the specifications of this subpart and will effectively achieve its purpose, the Secretary will approve the plan and notify the operator(s) submitting the plan of the approval. Approval may be conditioned upon such terms as the Secretary deems necessary to carry out the purpose of section 203 of the act.

(c) Where the Secretary has reason to believe that he will deny approval of a plan he will, prior to the denial, give reasonable notice in writing to the operator(s) of an opportunity to amend the plan. The notice shall specify the ground upon which approval is proposed to be denied.

(d) If a plan is denied approval, the Secretary shall advise the operator(s) in writing of the reasons for the denial.

§ 37.6 Chest roentgenographic examinations conducted by the Secretary.

(a) The Secretary will give chest roentgenograms or make arrangements with an appropriate person, agency, or institution to give the chest roentgenograms and with "A" or "B" readers to interpret the roentgenograms required under this subpart in the locality where the miner resides, at the mine, or at a medical facility easily accessible to a mining community or mining communities, under the following circumstances:

(1) Where, in the judgment of the Secretary, due to the lack of adequate medical or other necessary facilities or personnel at the mine or in the locality where the miner resides, the required roentgenographic examination cannot be given.

(2) Where the operator has not submitted an approvable plan.

(3) Where, after commencement of an operator's program pursuant to an approved plan and after notice to the operator of his failure to follow the approved plan and, after allowing 15 calendar days to bring the program into compliance, the Secretary determines and notifies the operator in writing that the operator's program still fails to comply with the approved plan.

(b) The operator of the mine shall reimburse the Secretary or other person, agency, or institution as the Secretary may direct, for the cost of conducting each examination made in accordance with this section.

(c) All examinations given or arranged by the Secretary will comply with the time requirements of § 37.3. Whenever the Secretary gives or arranges for the examinations of miners at a time, a written notice of the arrangements will be sent to the operator who shall post the notice on the mine bulletin board.

(d) Operators of mines selected by ALOSH to participate in the National Study of Coal Workers' Pneumoconiosis (an epidemiological study of respiratory diseases in coal miners) and who agree to cooperate will have all their miners afforded the opportunity to have a chest roentgenogram required hereunder at no cost to the operator. For future examinations and for mandatory examinations each participating operator shall submit an approvable plan.

§ 37.7 Transfer of affected miner to less dusty area.

(a) Any miner who, in the judgment of the Secretary based upon the interpretation of one or more of the miner's chest roentgenograms, shows category 1 (1/0, 1/1, 1/2), category 2 (2/1, 2/2, 2/3), or category 3 (3/2, 3/3, 3/4) simple pneumoconiosis, or complicated pneumoconiosis (ILO-U/C 1971 Classification) shall be afforded the option of transferring from his or her position to another position in an area of the mine where the concentration of respirable dust in the mine atmosphere is not more than 1.0 mg/m^3 of air, or if such level is not attainable in the mine, to a position in the mine where the concentration of respirable dust is the lowest attainable below 2.0 mg/m^3 of air.

(b) Any transfer under this section shall be in accordance with the procedures specified in Part 90 of Title 30, Code of Federal Regulations.

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978, as amended at 44 FR 23085, Apr. 18, 1979]

§ 37.8 Roentgenographic examination at miner's expense.

Any miner who wishes to obtain an examination at his or her own expense at an approved facility and to have submitted to NIOSH for him or her a complete examination may do so, provided that the examination is made no sooner than 6 months after the most recent examination of the miner submitted to ALOSH. ALOSH will provide an interpretation and report of the examinations made at the miner's expense in the same manner as if it were submitted under an operator's plan. Any change in the miner's transfer rights under the act which may result from this examination will be subject to the terms of § 37.7.

§ 37.20 Miner identification document.

As part of the roentgenographic examination, a miner identification document which includes an occupational history questionnaire shall be completed for each miner at the facility where the roentgenogram is made at the same time the chest roentgenogram required by this subpart is given.

SPECIFICATIONS FOR PERFORMING CHEST ROENTGENOGRAPHIC EXAMINATIONS

§ 37.40 General provisions.

(a) The chest roentgenographic examination shall be given at a convenient time and place.

(b) The chest roentgenographic examination consists of the chest roentgenogram, and a complete Roentgenographic Interpretation Form (Form CDC/NIOSH (M) 2.8), and miner identification document.

(c) A roentgenographic examination shall be made in a facility approved in accordance with § 37.42 by or under the supervision of a physician who regularly makes chest roentgenograms and who has demonstrated ability to make chest roentgenograms of a quality to best ascertain the presence of pneumoconiosis.

§ 37.41 Chest roentgenogram specifications.

(a) Every chest roentgenogram shall be a single posteroanterior projection at full inspiration on a 14- by 17-inch film. The film and cassette shall be capable of being positioned both vertically and horizontally so that the chest roentgenogram will include both apices and costophrenic angles. If a miner is too large to permit the above requirements, then the projection shall include both apices with minimum loss of the costophrenic angle.

(b) Miners shall be disrobed from the waist up at the time the roentgenogram is given. The facility shall provide a dressing area and for those miners who wish to use one, the facility shall provide a clean gown. Facilities shall be heated to a comfortable temperature.

(c) Roentgenograms shall be made only with a diagnostic X-ray machine having a rotating anode tube with a maximum of a 2 mm. source (focal spot).

(d) Except as provided in paragraph (e) of this section, roentgenograms shall be made with units having generators which comply with the following: (1) The generators of existing roentgenographic units acquired by the examining facility prior to July 27, 1973, shall have a minimum rating of 200 mA at 100 kVp.; (2) generators of units acquired subsequent to that date shall have a minimum rating of 300 mA at 125 kVp.

NOTE: A generator with a rating of 150 kVp. is recommended.

(e) Roentgenograms made with battery-powered mobile or portable equipment shall be made with units having a minimum rating of 100 mA at 110 kVp. at 500 Hz, or of 200 mA at 110 kVp. at 60 Hz.

(f) Capacitor discharge and field emission units may be used if the model of such units is approved by ALOSH for quality, performance, and safety. ALOSH will consider such units for approval when listed by a facility seeking approval under § 37.42 of this subpart.

(g) Roentgenograms shall be given only with equipment having a beam-limiting device which does not cause large unexposed boundaries. The beam limiting device shall provide rectangular collimation and shall be of the type described in part F of the suggested State regulations for the control of radiation or (for beam limiting devices manufactured after August 1, 1974) of the type specified in 21 CFR 1020.31. The use of such a device shall be discernible from an examination of the roentgenogram.

(h) to insure high quality chest roentgenograms:

(1) The maximum exposure time shall not exceed 1/20 of a second except that with single phase units with a rating less than 300 mA at 125 kVp. and subjects with chests over 28 cm. posteroanterior, the exposure may be increased to not more than 1/10 of a second;

(2) The source or focal spot to film distance shall be at least 6 feet;

(3) Medium-speed film and medium speed intensifying screens shall be used;

(4) Film-screen contact shall be maintained and verified at 6 month or shorter intervals;

(5) Intensifying screens shall be inspected at least once a month and

cleaned when necessary by the method recommended by the manufacturer;

(6) All intensifying screens in a cassette shall be of the same type and made by the same manufacturer;

(7) When using over 90 kV., a suitable grid or other means of reducing scattered radiation shall be used;

(8) The geometry of the radiographic system shall insure that the central axis (ray) of the primary beam is perpendicular to the plane of the film surface and impinges on the center of the film;

(9) A formal quality assurance program shall be established at each facility.

(i) Radiographic processing:

(1) Either automatic or manual film processing is acceptable. A constant time-temperature technique shall be meticulously employed for manual processing.

(2) If mineral or other impurities in the processing water introduce difficulty in obtaining a high-quality roentgenogram, a suitable filter or purification system shall be used.

(j) Before the miner is advised that the examination is concluded, the roentgenogram shall be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard roentgenogram, another shall be immediately made. All substandard roentgenograms shall be clearly marked as rejected and promptly sent to ALOSH for disposal.

(k) An electric power supply shall be used which complies with the voltage, current, and regulation specified by the manufacturer of the machine.

(l) A densitometric test object may be required on each roentgenogram for an objective evaluation of film quality at the discretion of ALOSH.

(m) Each roentgenogram made hereunder shall be permanently and legibly marked with the name and address or ALOSH approval number of the facility at which it is made, the social security number of the miner, and the date of the roentgenogram. No other identifying markings shall be recorded on the roentgenogram.

§ 37.42 Approval of roentgenographic facilities.

(a) Approval of roentgenographic facilities given prior to January 1, 1976, shall terminate upon August 1, 1978 unless each of the following conditions have been met:

(1) The facility must verify that it still meets the requirements set forth in the regulations for the second round of roentgenographic examinations (38 FR 20076) and it has not changed equipment since it was approved by NIOSH.

(2) From July 27, 1973, to January 1, 1976, the facility submitted to ALOSH at least 50 roentgenograms which were interpreted by one or more "B" readers not employed by the facility who found no more than 5 percent of all the roentgenograms unreadable.

(b) Other facilities will be eligible to participate in this program when they demonstrate their ability to make high quality diagnostic chest roentgenograms by submitting to ALOSH six or more sample chest roentgenograms made and processed at the applicant facility and which are of acceptable quality to the Panel of "B" readers. Applicants shall also submit a roentgenogram of a plastic step-wedge object (available on loan from ALOSH) which was made and processed at the same time with the same technique as the roentgenograms submitted and processed at the facility for which approval is sought. At least one chest roentgenogram and one test object roentgenogram shall have been made with each unit to be used hereunder. All roentgenograms shall have been made within 15 calendar days prior to submission and shall be marked to identify the facility where each roentgenogram was made, the X-ray machine used, and the date each was made. The chest roentgenograms will be returned and may be the same roentgenograms submitted pursuant to § 37.51.

NOTE: The plastic step-wedge object is described in an article by E. Dale Trout and John P. Kelley appearing in "The American Journal of Roentgenology, Radium Therapy and Nuclear Medicine," Vol. 117, No. 4, April 1973.

(c) Each roentgenographic facility submitting chest roentgenograms for approval under this section shall complete and include an X-ray facility document describing each X-ray unit to be used to make chest roentgenograms under the act. The form shall include: (1) The date of the last radiation safety inspection by an appropriate licensing agency or, if no such agency exists, by a qualified expert as defined in NCRP Report No. 33 (see § 37.43); (2) the deficiencies found; (3) a statement that all the deficiencies have been corrected; and (4) the date of acquisition of the X-ray unit. To be acceptable, the radiation safety inspection shall have been made within 1 year preceding the date of application.

(d) Roentgenograms submitted with applications for approval under this section will be evaluated by the panel of "B" Readers or by a qualified radiological physicist or consultant. Applicants will be advised of any reasons for denial of approval.

(e) ALOSH or its representatives may make a physical inspection of the applicant's facility and any approved roentgenographic facility at any reasonable time to determine if the requirements of this subpart are being met.

(f) ALOSH may require a facility periodically to resubmit roentgenograms of a plastic step-wedge object, sample roentgenograms, or a Roentgenographic Facility Document for quality control purposes. Approvals granted hereunder may be suspended or withdrawn by notice in writing when in the opinion of ALOSH the quality of roentgenograms or information submitted under this section warrants such action. A copy of a notice withdrawing approval will be sent to each operator who has listed the facility as its facility for giving chest roentgenograms and shall be displayed on the mine bulletin board adjacent to the operator's approved plan. The approved plan will be reevaluated by ALOSH in light of this change.

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978]

§ 37.43 Protection against radiation emitted by roentgenographic equipment.

Except as otherwise specified in section 37.41, roentgenographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used, shall conform to applicable State and Federal regulations (See 21 CFR Part 1000). Where no applicable regulations exist, roentgenographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used shall conform to the recommendations of the National Council on Radiation Protection and Measurements in NCRP Report No. 33 "Medical X-ray and Gamma-Ray Protection for Energies up to 10 MeV—Equipment Design and Use" (issued February 1, 1968), in NCRP Report No. 48, "Medical Radiation Protection for Medical and Allied Health Personnel" (issued August 1, 1976), and in NCRP Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of up to 10 MeV" (issued September 15, 1976). These documents are hereby incorporated by reference and made a part of this subpart. These documents are available for examination at ALOSH, 944 Chestnut Ridge Road, Morgantown, W. Va. 26505, and at the National Institute for Occupational Safety and Health, 5600 Fishers Lane, Rockville, Md. 20857. Copies of NCRP Reports Nos. 33, 48, and 49 may be purchased for $3, $4.50, and $3.50 each, respectively, from NCRP Publications, P.O. Box 30175, Washington, D.C. 20014.

SPECIFICATIONS FOR INTERPRETATION, CLASSIFICATION, AND SUBMISSION OF CHEST ROENTGENOGRAMS

§ 37.50 Interpreting and classifying chest roentgenograms.

(a) Chest roentgenograms shall be interpreted and classified in accordance with the ILO-U/C classification system and recorded on a Roentgenographic Interpretation Form (Form CDC/NIOSH (M) 2.8).

(b) Roentgenograms shall be interpreted and classified only by a physician who regularly reads chest roentgenograms and who has demonstrated proficiency in the use of the ILO-U/C classification system in accordance with § 37.51.

(c) All interpreters, whenever interpreting chest roentgenograms made under the act, shall have immediately available for reference a complete set of the ILO-U/C International Classification of Radiographs for Pneumoconioses, 1971.

NOTE: This set is available from the International Labour Office, Occupational Safety and Health Branch, CH 1211, Geneva 22, Switzerland.

(d) In all view boxes used for making interpretations:

(1) Fluorescent lamps shall be simultaneously replaced with new lamps at 6-month intervals;

(2) All the fluorescent lamps in a panel of boxes shall have identical manufacturer's ratings as to intensity and color;

(3) The glass, internal reflective surfaces, and the lamps shall be kept clean;

(4) The unit shall be so situated as to minimize front surface glare.

§ 37.51 Proficiency in the use of the ILO-U/C classification.

(a) First or "A" readers:

(1) Approval as an "A" reader shall continue if established prior to (insert) effective date of these regulations).

(2) Proficiency in the use of the ILO-U/C classification system shall be demonstrated by those physicians who desire to be "A" readers by either:

(i) Submitting to ALOSH from the physician's files six sample chest roentgenograms which are considered properly classified by the Panel of "B" readers. The six roentgenograms shall consist of two without pneumoconiosis, two with simple pneumoconiosis, and two with complicated pneumoconiosis. The films will be returned to the physician. The interpretations shall be on the Roentgenographic Interpretation Form (Form CDC/NIOSH (M) 2.8) (These may be the same roentgenograms submitted pursuant to § 37.42), or;

(ii) Satisfactory completion, since June 15, 1970, of a course approved by ALOSH on the ILO-U/C classification system or the UICC/Cincinnati classification system. As used in this subparagraph "UICC/Cincinnati classification" means the classification of the pneumoconioses devised in 1968 by a Working Committee of the International Union Against Cancer.

(b) Final or "B" readers:

(1) Approval as a "B" reader established prior to October 1, 1976, shall hereby be terminated.

(2) Proficiency in evaluating chest roentgenograms for roentgenographic quality and in the use of the ILO-U/C classification for interpreting chest roentgenograms for pneumoconiosis and other diseases shall be demonstrated by those physicians who desire to be "B" readers by taking and passing a specially designed proficiency examination given on behalf of or by ALOSH at a time and place specified by ALOSH. Each physician must bring a complete set of the ILO-U/C standard reference radiographs when taking the examination. Physicians who qualify under this provision need not be qualified under paragraph (a) of this section.

(c) Physicians who wish to participate in the program shall make application on an Interpreting Physician Certification Document (Form CDC/NIOSH (M) 2.12).

§ 37.52 Method of obtaining definitive interpretations.

(a) All chest roentgenograms which are first interpreted by an "A" or "B" reader will be submitted by ALOSH to a "B" reader qualified as described in § 37.51. If there is agreement between the two interpreters as defined in paragraph (b) of this section the result shall be considered final and reported to MSHA for transmittal to the miner. When in the opinion of ALOSH substantial agreement is lacking, ALOSH shall obtain additional interpretations from the Panel of "B" readers. If interpretations are obtained from two or more "B" readers, and if two or more are in agreement then the highest major category shall be reported.

(b) Two interpreters shall be considered to be in agreement when they both find either stage A, B, or C complicated pneumoconiosis, or their findings with regard to simple pneumoconiosis are both in the same major category, or are within one minor (ILO-U/C 12-point scale) category of each other. The higher of the two interpretations shall be reported.

§ 37.53 Notification of abnormal roentgenographic findings.

(a) Findings of, or findings suggesting, enlarged heart, tuberculosis, lung cancer, or any other significant abnormal findings other than pneumoconiosis shall be communicated by the first physician to interpret and classify the roentgenogram to the designated physician of the miner indicated on the miner's identifcation document. A copy of the communication shall be submitted to ALOSH. ALOSH will notify the miner to contact his or her physician when any physician who interprets and classifies the miner's roentgenogram reports significant abnormal findings other than pneumoconiosis.

(b) In addition, when ALOSH has more than one roentgenogram of a miner in its files and the most recent examination was interpreted to show enlarged heart, tuberculosis, cancer, complicated pneumoconiosis, and any other significant abnormal findings, ALOSH will submit all of the miner's roentgenograms in its files with their respective interprtations to a "B" reader. The "B" reader will report any significant changes or progression of disease or other comments to ALOSH and ALOSH shall submit a copy of the report to the miner's designated physician.

(c) All final findings regarding pneumoconiosis will be sent to the miner by MSHA in accordance with section 203 of the act (see 30 CFR Part 90). Positive findings with regard to pneumoconiosis will be reported to the miner's designated physician by ALOSH.

(d) ALOSH will make every reasonable effort to process the findings described in paragraph (c) of this section within 60 days of receipt of the information described in § 37.60 in a complete and acceptable form. The information forwarded to MSHA will be in a form intended to facilitate prompt dispatch of the findings to the miner. The results of an examination made of a miner will not be processed by ALOSH if the examination was made within 6 months of the date of a previous acceptable examination.

§ 37.60 Submitting required chest roentgenograms and miner identification documents.

(a) Each chest roentgenogram required to be made under this subpart, together with the completed roentgenographic interpretation form and the completed miner identification document, shall be sumitted together for each miner to ALOSH within 14 calendar days after the roentgenographic examination is given and become the property of ALOSH.

(b) If ALOSH deems any part submitted under paragraph (a) of this section inadequate, it will notify the operator of the deficiency. The operator shall promptly make appropriate arrangements for the necessary reexamination.

(c) Failure to comply with paragraph (a) or (b) of this section shall be cause to revoke approval of a plan or any other approval as may be appropriate. An approval which has been revoked may be reinstated at the discretion of ALOSH after it receives satisfactory assurances and evidence that all deficiencies have been corrected and that effective controls have been instituted to prevent a recurrence.

(d) Chest roentgenograms and other required documents shall be submitted only for miners. Results of preemployment physical examinations of persons who are not hired shall not be submitted.

(e) If a miner refuses to participate in all phases of the examination prescribed in this subpart, no report need be made. If a miner refuses to participate in any phase of the examination prescribed in this subpart, all the forms shall be submitted with his or her name and social security account number on each. If any of the forms cannot be completed because of the miner's refusal, it shall be marked "Miner Refuses," and shall be submitted. No submission shall be made, however, without a completed miner identification document containing the miner's name, address, social security number and place of employment.

REVIEW AND AVAILABILITY OF RECORDS

§ 37.70 Review of interpretations.

(a) Any miner who believes the interpretation for pneumoconiosis reported to him or her by MSHA is in error may file a written request with ALOSH that his or her roentgenogram be reevaluated. If the interpretation was based on agreement between an "A" reader and a "B" reader, ALOSH will obtain one or more additional interpretations by "B" readers as necessary to obtain agreement in accord with § 37.52(b), and MSHA shall report the results to the miner together with any rights which may accrue to the miner in accordance with § 37.7. If the reported interpretation was based on agreement between two (or more) "B" readers, the reading will be accepted as conclusive and the miner shall be so informed by MSHA.

(b) Any operator who is directed by MSHA to transfer a miner to a less dusty atmosphere based on the most recent examination made subsequent to August 1, 1978, may file a written request with ALOSH to review its findings. The standards set forth in paragraph (a) of this section apply and the operator and miner will be notified by MSHA whether the miner is entitled to the option to transfer.

§ 37.80 Availability of records.

(a) Medical information and roentgenograms on miners will be released by ALOSH only with the written consent from the miner, or if the miner is deceased, written consent from the miner's widow, next of kin, or legal representative.

(b) To the extent authorized, roentgenograms will be made available for examination only at ALOSH.

NOTE: The incorporation by reference provision in this document was approved by the Director of the Federal Register on June 1, 1973, and July 6, 1978, and the reference material is on file in the Federal Register Library.

Subpart—Autopsies

AUTHORITY: Sec. 508, 83 Stat. 803; 30 U.S.C. 957.

SOURCE: 36 FR 8870, May 14, 1971, unless otherwise noted.

§ 37.200 Scope.

The provisions of this subpart set forth the conditions under which the Secretary will pay pathologists to obtain results of autopsies performed by them on miners.

§ 37.201 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services.

(b) "Miner" means any individual who during his life was employed in any underground coal mine.

(c) "Pathologist" means

(1) A physician certified in anatomic pathology or pathology by the American Board of Pathology or the American Osteopathic Board of Pathology,

(2) A physician who possesses qualifications which are considered "Board of eligible" by the American Board of Pathology or American Osteopathic Board of Pathology, or

(3) An intern, resident, or other physician in a training program in pathology who performs the autopsy under the supervision of a pathologist as defined in paragraph (c) (1) or (2) of this section.

(d) "ALFORD" means the Appalachian Laboratory for Occupational Respiratory Diseases, Public Health Service, Department of Health and Human Services, Post Office Box 4257, Morgantown, WV 26505.

§ 37.202 Payment for autopsy.

(a) The Secretary will pay up to $200 to any pathologist who, after the effective date of the regulations in this part and with legal consent.

(1) Performs an autopsy on a miner in accordance with this subpart; and

(2) Submits the findings and other materials to ALFORD in accordance with this subpart within 180 calendar days after having performed the autopsy; and

(3) Receives no other specific payment, fee, or reimbursement in con-

nection with the autopsy from the miner's widow, his family, his estate, or any other Federal agency.

(b) The Secretary will pay to any pathologist entitled to payment under paragraph (a) of this section and additional $10 if the pathologist can obtain and submits a good quality copy or original of a chest roentgenogram (posteroanterior view) made of the subject of the autopsy within 5 years prior to his death together with a copy of any interpretation made.

[35 FR 13206, Aug. 19, 1970, as amended at 38 FR 16353, June 22, 1973]

§ 37.203 Autopsy specifications.

(a) Every autopsy for which a claim for payment is submitted pursuant to this part:

(1) Shall be performed consistent with standard autopsy procedures such as those, for example, set forth in the "Autopsy Manual" prepared by the Armed Forces Institute of Pathology, July 1, 1960. (Technical Manual No. 8-300. NAVMED P-5065, Air Force Manual No. 160-19.) Copies of this document may be borrowed from ALFORD.

(2) Shall include:

(i) Gross and microscopic examination of the lungs, pulmonary pleura, and tracheobronchial lymph nodes;

(ii) Weights of the heart and each lung (these and all other measurements required under this subparagraph shall be in the metric system);

(iii) Circumference of each cardiac valve when opened;

(iv) Thickness of right and left ventricles; these measurements shall be made perpendicular to the ventricular surface and shall not include trabeculations or pericardial fat. The right ventricle shall be measured at a point midway between the tricuspid valve and the apex, and the left ventricle shall be measured directly above the insertion of the anterior papillary muscle;

(v) Size, number, consistency, location, description and other relevant details of all lesions of the lungs;

(vi) Level of the diaphragm;

(vii) From each type of suspected pneumoconiotic lesion, representative microscopic slides stained with hematoxylin eosin or other appropriate stain, and one formalin fixed, paraffin-impregnated block of tissue; a minimum of three stained slides and three blocks of tissue shall be submitted. When no such lesion is recognized, similar material shall be submitted from three separate areas of the lungs selected at random; a minimum of three stained slides and three formalin fixed, paraffin-impregnated blocks of tissue shall be submitted.

(b) Needle biopsy techniques shall not be used.

§ 37.204 Procedure for obtaining payment.

Every claim for payment under this subpart shall be submitted to ALFORD and shall include:

(a) An invoice (in duplicate) on the pathologist's letterhead or billhead indicating the date of autopsy, the amount of the claim and a signed statement that the pathologist is not receiving any other specific compensation for the autopsy from the miner's widow, his surviving next-of-kin, the estate of the miner, or any other source.

(b) Completed PHS Consent, Release and History Form (See Fig. 1). This form may be completed with the assistance of the pathologist, attending physician, family physician, or any other responsible person who can provide reliable information.

(c) Report of autopsy:

(1) The information, slides, and blocks of tissue required by this subpart.

(2) Clinical abstract of terminal illness and other data that the pathologist determines is relevant.

(3) Final summary, including final anatomical diagnoses, indicating presence or absence of simple and complicated pneumoconiosis, and correlation with clinical history if indicated.

FIGURE 1

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE—NATIONAL COAL WORKERS' AUTOPSY STUDY

Consent, Release, and History Form Federal Coal Mine Health and Safety Act of 1969

I, ————————, (Name) ———— (Relationship) of ————————, (Name of deceased miner) do hereby authorize the performance of an autopsy (————————) (Limitation, if any, on autopsy) on said deceased. I understand that the report and certain tissues as necessary will be released to the United States Public Health Service and to ———————— (Name of Physician securing autopsy)

I understand that any claims in regard to the deceased for which I may sign a general release of medical information will result in the release of the information from the Public Health Service. I further understand that I shall not make any payment for the autopsy.

Occupational and Medical History

1. Date of Birth of Deceased ————. (Month, Day, Year)

2. Social Security Number of Deceased ——— ——— ———.

3. Date and Place of Death ————. (Month, Day, Year) ———————— (City, County, State).

4. Place of Last Mining Employment:
Name of Mine ————————————
Name of Mining Company ————————
Mine Address ————————————

5. Last Job Title at Mine of Last Employment ———————————————
(e.g., Continuous Miner Operator, motorman, foreman, etc.)

6. Job Title of Principal Mining Occupation (that job to which miner devoted the most number of years) ————————
(e.g., Same as above)

7. Smoking History of Miner:
(a) Did he ever smoke cigarettes? Yes —— No ————————————————
(b) If yes, for how many years?———— Years.
(c) If yes, how many cigarettes per day did he smoke on the average?———————— ——
(Number of) Cigarettes per day.
(d) Did he smoke cigarettes up until the time of his death? Yes —— No ——
(e) If no to (d), for how long before he died had he not been smoking cigarettes?

8. Total Years in Surface and Underground Employment in Coal Mining, by State (If known) ——, (Years) ———— (State).

9. Total Years in *Underground* Coal Mining Employment, by State (If known) ——, (Years) ———— (State).

————————————
(Signature)

————————————
(Address)

————————————
(Date)

Interviewer:

————————————————————

PART 38—DISASTER ASSISTANCE FOR CRISIS COUNSELING AND TRAINING

Sec.
38.1 Purpose; coordination.
38.2 Definitions.
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AUTHORITY: Sec. 413, Pub. L. 93-288. The Disaster Relief Act of 1974, 88 Stat. 157, 42 U.S.C. 5183, EO 11795, 39 FR 25939, as amended by EO 11910, 41 FR 15681.

Source: 41 FR 52052, Nov. 26, 1976, unless otherwise noted.

§ 38.1 Purpose; coordination.

(a) *Purpose.* This part establishes standards and procedures for the implementation of Section 413 of Pub. L. 93-288, the Disaster Relief Act of 1974 (42 U.S.C. 5183) which authorizes the provision, either directly or through financial assistance to State or local agencies or private mental health organizations, of:

(1) Professional counseling services to victims of a major disaster in order to relieve mental health problems caused or aggravated by such a major disaster or its aftermath; and

(2) Training of disaster workers to provide or assist in providing those professional counseling services.

(b) *Coordination.* The Secretary, acting through the National Institute of Mental Health, will, as provided in 24 CFR 2205.51, carry out section 413 of the Act and this part in coordination with and under the general policy guidance of, the Administrator of the Federal Disaster Assistance Administration. Contracts and grants awarded under this part are subject to all applicable provisions of the Act and the implementing regulations promulgated by the Administrator (24 CFR Part 2205).

BEST DOCUMENT AVAILABLE

§ 38.2 Definitions.

All terms not defined herein shall have the same meaning as given them in the Act. As used in this part:

(a) "Act" means the Disaster Relief Act of 1974 (42 U.S.C. 5121 et seq.).

(b) "Administrator" means the Administrator, Federal Disaster Assistance Administration (FDAA), Department of Housing and Urban Development, and any other person to whom he delegates the authority.

(c) "Contractor" means any public agency or private mental health organization which, pursuant to this part, contracts with the Secretary to provide professional mental health crisis counseling services or to provide mental health training for disaster workers.

(d) "Crisis" means the existence of any life situation resulting from a major disaster or its aftermath which so effects the emotional and mental equilibrium of a disaster victim that professional mental health counseling services should be provided to help preclude possible damaging physical or psychological effects.

(e) "Disaster workers" means mental health specialists such as psychiatrists, psychologists, psychiatric nurses, social workers, or qualified agents thereof.

(f) "Federal Coordinating Officer" means the person appointed by the Administrator to coordinate Federal assistance in a major disaster.

(g) "Governor" means the chief executive of a State.

(h) "Grantee" means any public agency or private nonprofit mental health organization which, pursuant to this part, is awarded a grant for the purpose of providing professional mental health crisis counseling services or mental health training for disaster workers.

(i) "Major disaster" means any hurricane, tornado, storm, flood, highwater, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, drought, fire, explosion, or other catastrophe in any part of the United States which, in the determination of the President, causes damage of sufficient severity and magnitude to warrant major disaster assistance under the Act above and beyond emergency services by the Federal Government, to supplement the efforts and available resources of the States, local governments, and disaster relief organizations, in alleviating the damage, loss, hardship, or suffering caused thereby.

(j) "Regional Director" means a director of a regional office of the Federal Disaster Assistance Administration (FDAA).

(k) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(l) "State" means any of the fifty States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Canal Zone, or the Trust Territory of the Pacific Islands.

(m) "State Coordinating Officer" means the person appointed by the Governor to act in cooperation with the appointed Federal Coordinating Officer.

(n) "Training" means the specific instruction which may be required to enable disaster workers to provide professional mental health crisis counseling to victims of a major disaster or its aftermath.

§ 38.3 Assistance; procedures, limitations.

(a) *Application.* In order to obtain assistance under this part, the Governor or his State Coordinating Officer must, not later than 60 days following a major disaster declaration by the President, file with the appropriate Regional Director a request which includes:

(1) An estimate of the number of disaster victims who may need professional mental health crisis counseling services and of the number of disaster workers who may need training in the provision of such services;

(2) Identification of the geographical areas in which the need exists;

(3) An estimate of the period during which assistance under this part will be required and of the total funds which will be required to provide such assistance;

(4) A description of the types of mental health problems caused or aggravated by the major disaster or its aftermath; and

(5) Identification of the State and local agencies and private mental health organizations capable of providing professional mental health crisis counseling to disaster victims or training of disaster workers.

(b) *Review, approval.* The Secretary, upon notification by the Administrator of a State request for assistance under this part, will conduct a review to determine the extent to which such assistance is needed to supplement assistance programs provided by State and local governments and private organizations and, on the basis of that review, prepare and submit a recommendation and report for consideration by the Administrator. Upon approval by the Administrator and his advancement of funds for carrying out the approved assistance, the Secretary may, within the limits of the funds advanced, provide the approved services either directly or through a grant or contract.

(c) *Eligibility for services.* (1) In order to be eligible for the professional mental health crisis counseling services available under this part an individual must:

(i) Have been located within the designated major disaster area or have been a resident of such area at the time of the major disaster or its aftermath; and

(ii) Have a mental health problem which was caused or aggravated by the major disaster or its aftermath.

(2) Disaster workers who are available on short notice to provide professional mental health crisis counseling services in a major disaster area are eligible for training under this part.

(d) *Time limitation.* Contracts and grants awarded under this part will not continue beyond 180 days after the first day services are provided pursuant to such contracts and grants, except that upon the recommendation of the Secretary (1) the Regional Director may extend the 180 day period for up to 30 days or (2) the Administrator may extend the 180 day period for more than 30 days.

§ 38.4 Contracts.

(a) *Eligibility.* Public agencies and private mental health organizations which are determined by the Secretary to be capable of providing the professional mental health crisis counseling services or mental health training of disaster workers needed as a result of a major disaster are eligible for the award of a contract under this part.

(b) *Use of local agencies.* Preference will be given to the extent feasible and practicable, to those agencies and organizations which are located or do business primarily in the area affected by the major disaster.

(c) *General Requirements.* Contracts under this part shall be entered into and carried out in accordance with the provisions of Chapters 1 and 3 of Title 41 of the Code of Federal Regulations and all other applicable laws and regulations.

(d) *Payments.* The Secretary shall from time to time make payments to the contractor of all or a portion of the contract award, either by way of reimbursement for expenses incurred or in advance for expenses to be incurred, to the extent he determines such payments are necessary to promote prompt initiation and advancement of the services to be provided under the contract. All payments not expended by the contractor within the period of the contract shall be returned to the Secretary.

(e) *Reports.* Contractors shall submit the following reports to the Secretary:

(1) Progress reports, to be submitted at the end of the first 30 days of the contract period and every 30 days therafter;

(2) A final report to be submitted within 60 days of the date upon which the contract terminates; and

(3) Such additional reports as the Secretary may prescribe including those which may be required to enable the Federal Coordinating Officer to carry out his functions.

§ 38.5 Grant assistance.

(a) *Eligibility.* Public agencies and private nonprofit mental health organizations which are determined by the Secretary to be capable of providing the professional mental health crisis counseling services or mental health training of disaster workers needed as a result of a major disaster are eligible for a grant award under this part.

(b) *Application.* The application shall contain:

(1) A proposed plan for the provision of the services for which grant assistance is requested;

(2) A proposed budget for the expenditure of the requested grant funds; and

(3) Such other pertinent information and assurances as the Secretary may require.

(c) *Grant awards.* (1) Preference will be given, to the extent feasible and practicable, to those public and private nonprofit agencies and organizations which are located or do business primarily in the area affected by the major disaster.

(2) Within the limits of the funds advanced by the Administrator, the amount of any grant award shall be determined on the basis of the Secretary's estimate of the sum necessary to carry out the grant purpose.

(3) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(d) *Other HHS regulations that apply.* Several other regulations apply to grants under this part. These include but are not limited to:

45 CFR Part 16—HHS grant appeals procedures

42 CFR Part 50, Subpart D—PHS grant appeals procedures

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates and other cost allocations)

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in federally assisted programs

45 CFR Part 91—Nondiscrimination on the basis of age in federally assisted programs

(e) *Expenditure of grant funds.* Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and the conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

(f) *Reports.* In exceptional circumstances, a grantee may be required to submit special progress reports, in addition to those otherwise required, relating to the conduct and results of the approved grant.

[41 FR 52052, Nov. 26, 1976, as amended at 45 FR 57396, Aug. 28, 1980]

§ 38.6 Nondiscrimination.

Attention is called to the requirements of 24 CFR 2205.13 relating to nondiscrimination on the grounds of race, religion, sex, color, age, economic status, or national origin in the provision of disaster assistance.

§ 38.7 Nonliability.

Attention is called to section 308 of the Act (42 U.S.C. 5148) which provides that the Federal Government shall not be liable for any claim based upon the exercise or performance of or the failure to exercise or perform a discretionary function or duty on the part of a Federal agency or an employee of the Federal Government in carrying out the provisions of the Act.

§ 38.8 Criminal and civil penalties.

Attention is called to section 317 of the Act (42 U.S.C. 5157) which provides:

> (a) Any individual who fraudulently or willfully misstates any fact in connection with a request for assistance under this Act shall be fined not more than $10,000 or imprisoned for not more than one year or both for each violation.
>
> (b) Any individual who knowingly violates any order or regulation under this Act shall be subject to a civil penalty of not more than $5,000 for each violation.

(c) Whoever knowingly misapplies the proceeds of a loan or other cash benefit obtained under any section of this Act shall be subject to a fine in an amount equal to one and one half times the original principal amount of the loan or cash benefit.

§ 38.9 Federal audits.

The Secretary, the Administrator, and the Comptroller General of the United States, or their duly authorized representatives shall have access to any books, documents, papers, and records that pertain to Federal funds, equipment, and supplies received under this part for the purpose of audit and examination.

SUBCHAPTER D—GRANTS

PART 50—POLICIES OF GENERAL APPLICABILITY

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Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

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AUTHORITY: Secs. 215, 1001, 1006 Public Health Service Act, as amended, 42 U.S.C. 216, 300, 300a-4; sec. 501 of Pub. L. 95-134, 91 Stat. 1164 (48 U.S.C. 1469a); sec. 1743 of Pub. L. 97-35, 95 Stat. 763 (31 U.S.C. 1243 note).

Subpart A—[Reserved]

Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

SOURCE: 43 FR 52165, Nov. 8, 1978, unless otherwise noted.

§ 50.201 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

§ 50.202 Definitions.

As used in this subpart:

"Arrange for" means to make arrangements (other than mere referral of an individual to, or the mere making of an appointment for him or her with, another health care provider) for the performance of a medical procedure on an individual by a health care provider other than the program or project.

"Hysterectomy" means a medical procedure or operation for the purpose of removing the uterus.

"Institutionalized individual" means an individual who is (1) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness, or (2) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

"Mentally incompetent individual" means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose unless he or she has been declared competent for purposes which include the ability to consent to sterilization.

"Public Health Service" means the Health Services Administration,

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Health Resources Administration, National Institutes of Health, Center for Disease Control, Alcohol, Drug Abuse and Mental Health Administration and all of their constituent agencies.

The "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"Sterilization" means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

§ 50.203 Sterilization of a mentally competent individual aged 21 or older.

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of an individual only if the following requirements have been met:

(a) The individual is at least 21 years old at the time consent is obtained.

(b) The individual is not a mentally incompetent individual.

(c) The individual has voluntarily given his or her informed consent in accordance with the procedures of § 50.204 of this subpart.

(d) At least 30 days but not more than 180 days have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of premature delivery or emergency abdominal surgery, if at least 72 hours have passed after he or she gave informed consent to sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 50.204 Informed consent requirement.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this section and § 50.205 of this subpart.

(a) A person who obtains informed consent for a sterilization procedure must offer to answer any questions the individual to be sterilized may have concerning the procedure, provide a copy of the consent form, and provide orally all of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw consent to the procedure any time before the sterilization without affecting his or her right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled:

(2) A description of available alternative methods of family planning and birth control;

(3) Advice that the sterilization procedure is considered to be irreversible;

(4) A thorough explanation of the specific sterilization procedure to be performed;

(5) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(6) A full description of the benefits or advantages that may be expected as a result of the sterilization; and

(7) Advice that the sterilization will not be performed for at least 30 days except under the circumstances specified in § 50.203(d) of this subpart.

(b) An interpreter must be provided to assist the individual to be sterilized if he or she does not understand the language used on the consent form or the language used by the person obtaining the consent.

(c) Suitable arrangements must be made to insure that the information specified in paragraph (a) of this section is effectively communicated to any individual to be sterilized who is blind, deaf or otherwise handicapped.

(d) A witness chosen by the individual to be sterilized may be present when consent is obtained.

(e) Informed consent may not be obtained while the individual to be sterilized is:

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

(f) Any requirement of State and local law for obtaining consent, except one of spousal consent, must be followed.

§ 50.205 Consent form requirements.

(a) *Required consent form.* The consent form appended to this subpart or another consent form approved by the Secretary must be used.

(b) *Required signatures.* The consent form must be signed and dated by:

(1) The individual to be sterilized; and

(2) The interpreter, if one is provided; and

(3) The person who obtains the consent; and

(4) The physician who will perform the sterilization procedure.

(c) *Required certifications.* (1) The person obtaining the consent must certify by signing the consent form that:

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify by signing the consent form, that:

(i) Shortly before the performance of the sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized. Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed. If premature delivery occurs or emergency abdominal surgery is required within the 30-day period, the physician must certify that the sterilization was performed less than 30 days but not less than 72 hours after the date of the individual's signature on the consent form because of premature delivery or emergency abdominal surgery, as applicable. In the case of premature delivery, the physician must also state the expected date of delivery. In the case of emergency abdominal surgery, the physician must describe the emergency.

(3) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally, read the consent form and explained its contents and to the best of the interpreter's knowledge and belief, the individual to be sterilized understood what the interpreter told him or her.

§ 50.206 Sterilization of a mentally incompetent individual or of an institutionalized individual.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any mentally incompetent individual or institutionalized individual.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any hysterectomy solely for the purpose of rendering an individual permanently incapable of reproducing or where, if there is more than one purpose to the procedure, the hysterectomy would not be performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) Except as provided in paragraph (c) of this section, programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy not covered by paragraph (a) of this section only if:

(1) The person who secures the authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will

make her permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(c)(1) A program or project is not required to follow the procedures of paragraph (b) of this section if either of the following circumstances exists:

(i) The individual is already sterile at the time of the hysterectomy.

(ii) The individual requires a hysterectomy because of a life-threatening emergency in which the physician determines that prior acknowledgment is not possible.

(2) If the procedures of paragraph (b) of this section are not followed because one or more of the circumstances of paragraph (c)(1) exist, the physician who performs the hysterectomy must certify in writing:

(i) That the woman was already sterile, stating the cause of that sterility; or

(ii) That the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure or hysterectomy it performs or arranges, meet all requirements of this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance adminstered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary is used.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, and as applicable, either acknowledgments of receipt of hysterectomy information or certification of an exception for hysterectomies.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.210 Review of regulation.

The Secretary will request public comment on the operation of the provisions of this subpart not later than 3 years after their effective date.

Appendix

APPENDIX—REQUIRED CONSENT FORM

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from ———————— (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a ————————. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on — (day), ——— (month), —— (year).

I, ————, hereby consent of my own free will to be sterilized by ———— by a method called ————. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

Signature ————————————
Date: ————————————
(Month, day, year)

You are requested to supply the following information, but it is not required:

Race and ethnicity designation (please check)
Black (not of Hispanic origin) ————
Hispanic ————————————
Asian or Pacific Islander ————
American Indian or Alaskan native ———
White (not of Hispanic origin) ————

Interpreter's Statement

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in ———— language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

Interpreter ————————————
Date ————————————

State of Person Obtaining Consent

Before ———— (name of individual), signed the consent form, I explained to him/her the nature of the sterilization operation ————, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure.

Signature of person obtaining consent ———
Date ————————————
Facility ————————————
Address ————————————

Physician's Statement

Shortly before I performed a sterilization operation upon ———— (name of individual to be sterilized), on ——— (date of sterilization), ———— (operation), I explained to him/her the nature of the sterilization operation ———— (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(*Instructions for use of alternative final paragraphs:* Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested):

☐ Premature delivery

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Individual's expected date of delivery: ——

☐ Emergency abdominal surgery:

(Describe circumstances): ——

Physician ——

Date ——

YOUR STERILIZATION OPERATION: INFORMATION FOR WOMEN

WHY THIS PAMPHLET IS IMPORTANT TO YOU

Sterilization is an operation which is intended to make it impossible for you to ever become pregnant. This pamphlet describes the different types of sterilization operations, their benefits, their discomforts, and their risks. You should read the pamphlet completely.

Both men and women can be sterilized. This pamphlet is about sterilization operations for a woman. (Ask your doctor or clinic for the pamphlet on sterilization for a man.)

If the Federal Government is to pay for your sterilization, certain conditions must be met. They are listed on page . The purpose of these conditions is to ensure that you understand sterilization and that you choose freely to have this operation.

MAKING UP YOUR MIND

Sterilization must be considered permanent. For nearly all women, once this operation has been done, it can never be undone. Some doctors try to undo a sterilization by rejoining the tubes. This is a difficult and expensive operation and it doesn't work very often. Some people call sterilization "tying the tubes." But don't think the tubes can be untied! They can't. So it's not a good idea to think your sterilization can be undone.

Make sure you do not want to bear children under any circumstances before you decide to be sterilized. Are you sure you would not want to bear children even if one of your present children died? Or your husband died? Or you got divorced and remarried? Be sure, before you decide to be sterilized.

No one can force you to be sterilized! Don't let anyone push you into it. If you do not want to be sterilized, no one can take away any of your Federal benefits such as welfare, Social Security, or health care—including sterilization at a later date. No one can force you to be sterilized as a condition for delivering your baby or performing an abortion.

To have this operation paid for with Federal funds, you must be at least 21 years old. If you are married, you should discuss the operation with your husband. However, his consent is not required if Medicaid or any other Federal Government program is going to pay for your operation. Your consent to sterilization cannot be obtained while you are in the hospital for childbirth or abortion, or if you are under the influence of alcohol or other substances that affect your state of awareness.[1]

You must sign the consent form at least 30 days before you plan to have the operation. This is so you will have at least 30 days to think it over and discuss it with your family and others. You can change your mind any time before the operation and can cancel your appointment if you do.

OTHER METHODS OF BIRTH CONTROL

There are many other ways to avoid pregnancy. Before you decide to be sterilized, think about these other methods of birth control.

TEMPORARY METHODS OF BIRTH CONTROL

The following methods of birth control are temporary. This means that when you or your partner stop using them you can become pregnant. Temporary methods of birth control are effective only if you use them according to instructions. If you think you might want to become pregnant later, you should use a temporary method of birth control instead of sterilization.

Ask your doctor or clinic for pamphlets and counseling on any of these temporary methods of birth control if you want them. If you decide you want a temporary method of birth control, ask for it today.

Birth control pill—A pill you take regularly which makes you 98 percent certain you will not get pregnant. It is usually safe, but has occasional side effects and rare serious complications. The pill has been linked in some women with minor side effects such as darkening of the skin of the face, nausea, and vaginal discharge. More serious complications which occur infrequently include depression, increased tendency for abnormal blood clotting, increased risk of heart attack and stroke (especially among women over age 35 who smoke), and a small increased risk of liver or gall bladder disease.

Loop, coil, intrauterine device (IUD)—A small piece of plastic a doctor or family planning specialist inserts into your uterus (womb) which makes you 96 percent certain you will not get pregnant. It is usually very safe, but has occasional side effects and rare serious complications. IUD use has been linked in some women with irregular periods, cramps, and increased risk of infection of the uterus.

Diaphragm with contraceptive jelly or cream—A cup of rubber or soft plastic you place in your vagina each time before inter-

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[1] This condition, the minimum age of 21, and the 30-day waiting period must be met if the Federal Government is to pay for your sterilization.

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course. Contraceptive jelly or cream must be used with the diaphragm for it to be effective. Sometimes it fails if it is not used properly (85-90 percent effective) and you can get pregnant anyway, but it has no risk of serious complications.

Contraceptive foam, foaming tablet—A foam (which looks like shaving cream) or a tablet you place in your vagina each time before intercourse. Sometimes it fails (85 percent effective) and you can get pregnant anyway. It occasionally has minor side effects.

Condom, prophylactic—A thin sheath of rubber the man places over his penis each time before intercourse. Sometimes it fails (90 percent effective) and you can get pregnant anyway, but there is no risk of serious complications. A condom and contraceptive foam or diaphragm can be used at the same time for extra protection.

Natural methods—A type of birth control in which you do not have intercourse on the 8-15 days each month when you are likely to get pregnant. It is sometimes hard to tell when these days occur and effectiveness depends on proper instruction and motivation. The sympto-thermal method (90 percent effective) is an example of natural methods. It involves keeping a chart of your body temperature and checking your cervical mucus. Effectiveness depends upon the care with which you follow it. Some people think of natural methods as only rhythm (the calendar method), but this method is no longer recommended by experts in natural methods. There is no risk of complications with natural methods.

STERILIZATION FOR A MAN

A man can be sterilized by an operation called a vasectomy. This operation is intended to make it impossible for him to ever father children. It is simpler, quicker, and safer than the sterilization operation for a woman, so you and your partner may decide that it is better for him to have the sterilization operation. (Ask your doctor or clinic for the pamphlet on sterilization for a man.)

WHAT ABOUT ABORTION?

Abortion does not prevent pregnancy. It is an operation to stop a pregnancy which has already started. It should be done during the first 3 months of pregnancy. It can be done later, but it is more expensive, less safe, and usually requires that you stay in a hospital. Abortion works to stop a pregnancy almost 100 percent of the time. There are some discomforts and occasional complications (sometimes serious) with abortion. When this pamphlet was written, Medicaid and some other Federal Government programs would pay for abortions only in certain cases. Ask your doctor or clinic.

WHEN CAN A WOMAN HAVE A STERILIZATION OPERATION?

A sterilization operation can be done at different times. A talk with your doctor or clinic can help you to decide what might be most suitable for you.

A woman can have a sterilization operation at any time in her life. This means a woman can have a sterilization operation at any time she wants. It doesn't matter if she is not married or doesn't have children. It is up to her.

A woman can have a sterilization operation right after having a baby. This means that a woman may want to be sterilized while she is in the hospital for the delivery. A woman should think about this early in her pregnancy because in order for the sterilization to be paid for with Federal funds she must sign the consent form at least 30 days before the baby is due. If the woman delivers prematurely or has emergency abdominal surgery at least 72 hours after she has signed the consent form, she does not need to wait 30 days, and the sterilization may be performed at the same time as the other surgery. She should be sure that she would not want to have children again even if the baby did not live very long after birth.

A woman can have a sterilization operation at the same time she has a baby by cesarean section. Sometimes a baby has to be delivered by an operation through the abdomen. This is called a cesarean section. A sterilization operation can be done at the same time through the same incision, but the woman must make up her mind at least 30 days before the baby is due.

A woman can have a sterilization operation right after she has an abortion if she has signed the consent form at least 30 days previously. Remember that an abortion which is delayed may be more difficult and carry more risk. If a woman is not sure about the sterilization, she can still have an abortion, and then decide to be sterilized or not at a later time.

FACTS ABOUT THE OPERATION

The surgical method of birth control is called a tubal sterilization or tubal ligation. In this operation the doctor blocks or separates each of your two tubes so that your eggs cannot travel through them from your ovaries to your uterus. Blocking the tubes makes pregnancy impossible. Menstruation (monthly bleeding period) continues as before. Tubal sterilization will not change your hormones (will not cause change of life).

IS THE OPERATION GUARANTEED TO WORK?

Tubal sterilization works almost all the time. This means that only from 2 to 5 out of every 1,000 women who have the oper-

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ation will still get pregnant. This is usually because the two ends of the tubes have grown back together. It is more than 99 percent effective—higher than all other methods of birth control for women. You should use some temporary method of birth control until you have your operation. Your doctor will try to be certain you are not already pregnant at the time of the operation.

FOUR TYPES OF TUBAL STERILIZATION

1. Laparotomy, mini-laparotomy;
2. Laparoscopy;
3. Postpartum tubal ligation; and
4. Vaginal tubal ligation.

The operation you have depends on your health and your doctor. Talk to him or her about which operation you will have.

LAPAROTOMY, MINI-LAPAROTOMY

In both of these operations, the doctor makes an incision (cut) in the lower portion of your abdomen. The difference between the two is the length of the incision and the extensiveness of the surgery. In a mini-laparotomy the incision is very short (1 or 2 inches) and leaves only a small scar. In a laparotomy it is much longer (3 to 5 inches) and leaves a longer scar. Ask your doctor which method he or she uses.

Through the incision on the abdomen, the doctor can reach both tubes, one at a time. The doctor can either remove a section and then use surgical thread to tie the tubes shut or seal them with electric current, bands, or clips. After the tubes are sealed, the incision on your abdomen is stitched closed.

The operation, including the anesthesia, takes about 30 minutes. With a mini-laparotomy, you will probably stay in the hospital less than 24 hours, and be back to normal in 2 or 3 days. With a laparotomy, you will be in the hospital 4 days or more, and it may be 2 weeks before you feel back to normal.

LAPAROSCOPY

Using a special needle, the doctor inflates your abdomen with a harmless gas which pushes your intestines away from your uterus and tubes.

The doctor then makes a small incision about one-half inch long near your navel. A "laparoscope," or special telescope, is inserted through this incision. It is a thin metal tube with a light on it which allows the doctor to see your tubes, and through which the doctor can insert the operating instrument. Your tubes are sealed by the use of electric current, bands, or clips. Some doctors make a second small incision at the pubic hairline to insert the operating instrument.

After the gas in your abdomen is released, the incision is closed.

The operation, including the anesthesia, takes about 30 minutes. You will probably stay in the hospital less than 24 hours and be back to normal in 2 or 3 days. Because of the gas, you may feel a pain in your neck or shoulders and you may seem bloated after the surgery. This goes away after a day or two.

POSTPARTUM TUBAL LIGATION

This operation is done in the hospital shortly after a woman has a baby. The doctor makes a small incision below your navel. The doctor then closes off a section of each tube using surgical threads. After the tubes are tied, a small section between the ties is removed. The incision below your navel is stitched closed.

The operation, including the anesthesia, usually takes about 30 minutes. Having the operation may make your hospital stay a day or two longer. How fast you get better will depend on how you feel after having the baby.

VAGINAL TUBAL LIGATION

In this operation, the doctor makes a small incision far back in the vagina. Through this, the doctor finds your tubes, then closes them off either with electric current, bands, or clips, or by removing a small section and closing the ends with surgical threads. After the tubes are sealed, the incision in your vagina is stitched closed.

Sometimes the doctor will use a metal tube with a light (called a culdoscope) to see your tubes and seal them.

The operation, including the anesthesia, usually takes about 30 minutes. Your stay in the hospital will probably be less than 24 hours. You should be back to normal in 2 or 3 days. After this type of operation, you should not have intercourse for 3 to 4 weeks so the vagina can heal.

THE ANESTHETIC

With any method of sterilization, you will first be given an anesthetic which is a drug to keep you from feeling pain during the operation. A medical person who specializes in anesthesia may do this part of the operation.

Sometimes the operation is done under "general" anesthesia. That means you will be asleep during the operation. The drugs used are a gas which you inhale and/or a liquid given to you by injection.

Sometimes the operation is done under "local" anesthesia or "spinal" anesthesia. That means you are awake, but do not feel any pain.

A local anesthetic is given by injection into the skin. It makes your skin numb.

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A spinal anesthetic is given by injection low in the spine. This type of injection makes you feel numb from the waist down.

With local or spinal anesthesia, you may also be given pills or another injection to help you relax.

You should have a chance to discuss and participate in the decision regarding your type of anesthesia with someone before your operation.

BENEFITS OF TUBAL STERILIZATION

The benefits of tubal sterilization are:

You never have to use a temporary method of birth control again (such as the pill or the IUD).

You don't have to worry about getting pregnant.

DISCOMFORTS AND RISKS

No matter which type of operation you have, you can expect to feel pain and soreness in your abdomen for a few days. You can take medicine to help relieve the discomfort.

If you had general anesthesia, you may have a sore throat for a day or two from the tube used to keep your airway open while you were asleep. This goes away quickly and is not serious. Spinal anesthesia may give some persons a temporary headache.

Sterilization operations have some risks, including a very small risk of death. This is true of any type of operation. serious problems happen rarely. Most of the time serious problems can be treated and cured by the doctor without further surgery; however, an operation may be necessary to correct some of these problems.

Some of the medical problems you could have during or after a sterilization operation:

1. You may bleed from the incision on your skin or in your vagina.

2. You may bleed inside your abdomen. (Another operation may be necessary to stop the bleeding.)

3. You may get an infection on or near the stitches or inside your abdomen.

4. The operation may not make you sterile. The operation cannot be guaranteed 100 percent to make you sterile. From 2 to 5 out of 1,000 women get pregnant after the operation.

5. As in other operations, the anesthetic drugs used to put you to sleep or to make the operation painless may cause problems. You may vomit while under anesthesia, and pneumonia may result.

Go back to your doctor at once if you get fever and/or severe pain in your abdomen. Either of these could be signs that you have an infection.

WHAT ABOUT HYSTERECTOMY?

Hysterectomy is different from tubal sterilization. Instead of blocking off the tubes, the whole uterus is taken out. A hysterectomy should be done only when there is a disease of the woman's uterus or some other problem that can only be treated by removing the uterus.

A hysterectomy is a much more serious operation than a tubal sterilization. A hysterectomy takes much longer to do, and the woman is in the hospital longer than with a tubal sterilization. There are more discomforts, and there is a greater chance of serious health problems. For these reasons, neither medicaid nor any other Federal program will pay for a hysterectomy if the only reason you are having it is to avoid bearing children, and you have no disease of your uterus.

SUMMARY

If you are sure you do not want to bear children and you want to become permanently sterile, then tubal sterilization is a safe, effective operation. It requires a relatively brief stay in the hospital, and problems are rare.

IF YOU HAVE QUESTIONS

If there is anything that is not clear to you, or anything you are worried about, it is important that you bring up these questions. All of your questions should be answered to your satisfaction before the operation.

REMEMBER

You may change your mind at any time before the operation. Make sure you do not wish to bear children under any circumstances before you decide to be sterilized.

RULES FOR STERILIZATION OPERATIONS FUNDED BY THE FEDERAL GOVERNMENT

You must be at least 21 years old.

You must wait at least 30 days to have the operation after you sign the consent form except in instances of premature delivery or emergency abdominal surgery that take place at least 72 hours after consent is obtained.

Your consent to sterilization cannot be obtained while you are in the hospital for childbirth or abortion, or under the influence of alcohol or other substances that affect your state of awareness.

You may, if you choose, bring someone with you when you sign the consent form.

Your consent is effective for 180 days from the date you sign the consent form.

Be sure to take this pamphlet and your signed consent form with you.

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YOUR STERILIZATION OPERATION: INFORMATION FOR MEN

WHY THIS PAMPHLET IS IMPORTANT TO YOU

Sterilization is an operation which is intended to make it impossibe for you to ever father children. This pamphlet describes the sterilization operation for a man—called vasectomy—its benefits, its discomforts, and its risks. You should read the pamphlet completely.

Both men and women can be sterilized. (Ask your doctor or clinic for the pamphlet on sterilization for a woman.) The man's operation is easier, safer, and less expensive than the woman's operation.

If the Federal Government is to pay for your sterilization, certain conditions must be met. They are listed on page ——. The purpose of these conditions is to ensure that you understand sterilization and that you choose freely to have this operation.

MAKING UP YOUR MIND

Sterilization must be considered permanent. For nearly all men, once this operation has been done, it can never be undone. Some doctors try to undo a vasectomy by rejoining the tubes. This is a difficult and expensive operation and it doesn't work very often. So it's not a good idea to think your vasectomy can be undone.

Some men have heard about storing their sperm in sperm banks to use later. There is not enough known right now about keeping sperm to show that it works.

Make sure you do not want to father children under any circumstances before you decide to be sterilized. Are you sure you would not want to father children even if one of your present children died? Or your wife died? Or you got divorced and remarried? Be sure, before you decide to be sterilized.

No one can force you to be sterilized! Don't let anyone push you into it. If you do not want to be sterilized, no one can take away any of your Federal benefits such as welfare, Social Security, or health care—including sterilization at a later date.

To have this operation paid for with Federal funds, you must be at least 21 years old. If you are married, you should discuss the operation with your wife. However, her consent is not required if Medicaid or any other Federal program is going to pay for your operation.

You must sign the consent form at least 30 days before you have the operation.[1] This is so you will have at least 30 days to think it over and discuss it with your family and others. You can change your mind any time before the operation and can cancel your appointment if you do.

OTHER METHODS OF BIRTH CONTROL

There are other ways to avoid fathering children. Before you decide to be sterilized, think about these other methods of birth control.

TEMPORARY METHODS OF BIRTH CONTROL

The following methods of birth control are temporary. This means that when you or your partner stop using them you can father children. Temporary methods of birth control are effective only if you use them according to instructions. If you think you might want to father children later, you should use a temporary method of birth control instead of sterilization.

Ask your doctor or clinic for pamphlets and counseling on any of these temporary methods of birth control if you want them. If you decide you want a temporary method of birth control, ask for it today.

Condom, prophylactic—A thin sheath of rubber the man places over his penis each time before intercourse. Sometimes it fails (90 percent effective) and the woman can get pregnant anyway, but there is no risk of serious complications. A condom and contraceptive foam or diaphragm can be used at the same time for extra protection.

Birth control pill—A pill the woman takes regularly which makes her 98 percent certain she will not get pregnant. It is usually safe, but has occasional side effects and rare serious complications. The pill has been linked in some women with minor side effects such as darkening of the skin of the face, nausea, and vaginal discharge. More serious complications which occur infrequently include depression, increased tendency for abnormal blood clotting, increased risk of heart attack and stroke (especially among women over age 35 who smoke), and a small increased risk of liver of gall bladder disease.

Loop, coil, intrauterine devise (IUD)—A small piece of plastic a doctor or family planning specialist inserts into the woman's uterus (womb) which makes her 96 percent certain she will not get pregnant. It is usually very safe, but has occasional side effects and rare serious complications. IUD use has been linked in some women with irregular periods, cramps, and increased risk of infection of the uterus.

Diaphragm with contraceptive jelly or cream—A cup of rubber or soft plastic the woman places in her vagina each time before intercourse. Contraceptive jelly or cream must be used with the diaphragm for

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[1] This condition must be met if the Federal Government is to pay for your sterilization.

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it to be effective. Sometimes it fails if it is not used properly (85-90 percent effective) and she can get pregnant anyway, but it has no risk of serious complications.

Contraceptive foam, foaming tablet—A foam (which looks like shaving cream) or a tablet the woman places in her vagina each time before intercourse. Sometimes it fails (85 percent effective) and she can get pregnant anyway. It occasionally has minor side effects.

Natural methods—A type of birth control in which the woman does not have intercourse on the 8-15 days each month when she is likely to get pregnant. It is sometimes hard to tell when these days occur, and effectiveness depends on proper instruction and motivation. Effectiveness can be as high as 90 percent for the sympto-thermal method if used properly. There is no risk of complications with natural methods.

STERILIZATION FOR A WOMAN

A woman can be sterilized by an operation called a tubal ligation. This operation is intended to make it impossible for her to ever bear children. Tubal ligation is more complex and not as safe as the sterilization operation for a man. (Ask your doctor or clinic for the pamphlet on sterilization for a woman.)

WHEN CAN A MAN HAVE A STERILIZATION OPERATION?

A man can have a sterilization operation at any time in his life. This means a man can have a sterilization operation at any time he wants. It doesn't matter if he is not married or doesn't have children. It is up to him.

FACTS ABOUT THE OPERATION

The surgical method of birth control is called a vasectomy. It is done in a doctor's office or clinic. Under local anesthesia, the doctor closes off the sperm duct (tubes) so that sperm cannot get through these ducts into the semen (the fluid ejected at climax). When there are no sperm in the semen, you cannot cause a pregnancy. Only the sperm are blocked, not the liquid part of the semen. You will still ejaculate (eject fluid) as before. Vasectomy will not change your hormones. (NOTE: Vasectomy is not castration. The testicles are not removed.)

HOW A VASECTOMY IS DONE

First, a local anesthetic is given by injection into your skin on each side of the scrotum (sac) to make it temporarily numb. You will feel mild pain, like a pin prick, for a few seconds.

Once the area is numb, the doctor makes one or two very small (one-half inch) incisions (cuts). Through these, the doctor reaches the sperm ducts, cuts them, and closes them off. The incisions on the skin are then closed with stitches. The scars can hardly be seen after a couple of weeks.

The operation, including anesthesia, usually takes about 15-20 minutes. You can usually go home shortly after the operation.

IS THE OPERATION GUARANTEED TO WORK?

Vasectomy works almost all the time. This means that only about 1 out of 1,000 men who have the operation will still be able to get a woman pregnant. This is usually because the two ends of the ducts have grown back together. It is more than 99 percent effective—higher than all other methods of birth control for men. You should use some temporary method of birth control until you have your operation.

You are not immediately sterile after your vasectomy. There will still be some sperm in your ducts until you have ejaculated 10 or more times after your operation. During this time, you can still cause a pregnancy. So it is important that you and your partner use another good method of birth control until tests of your semen show it contains no more sperm. Your doctor will tell you when to return for a simple test of your semen under a microscope.

BENEFITS OF VASECTOMY

The benefits of vasectomy are:

You never have to use a temporary method of birth control again (such a rubber).

You never have to worry about making a woman pregnant.

DISCOMFORTS AND RISKS

Vasectomy is considered a safe and simple operation, but there is a small chance you will have some medical problems afterwards. You can expect some soreness after the operation. This is not serious and will go away after a few days.

Serious medical problems happen rarely. Most of the time they can be treated and cured by the doctor without further surgery; however, an operation may be necessary to correct some of them. Some of the medical problems you could have after a sterilization operation:

1. You may have swelling around the incision on your skin. This happens right after the operation and is only temporary.

2. You may have bleeding under the skin which causes a bruise. This usually clears up by itself. Ice bags are often recommended to reduce the chance of this bleeding.

3. You may get an infection either on the skin or inside the scrotum. It is important to follow the doctor's recommendations about the care and cleansing of the incision while it is healing.

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4. The operation may not make your sterile. The operation cannot be guaranteed 100 percent to make you sterile. About 1 out of 1,000 men who have the operation will still be able to get a woman pregnant.

Go back to your doctor at once if swelling lasts for more than a few days, or you have a fever, or you have severe pain.

A very few men (4 out of 1,000 who have had the operation) said they had sexual problems after the operation. These were either decreased sexual desire or inability to have an erection. There is no medical explanation for these rare symptoms, and they are believed to result from an emotional reaction to the operation.

Some doctors have reported long term medical problems, but so far research has not proven that such problems really exist.

SUMMARY

If you are sure you do not want to father children and you want to become permanently sterile, then vasectomy is a safe, effective operation. It requires only a short time in a doctor's office or clinic, and problems are rare.

IF YOU HAVE QUESTIONS

If there is anything that is not clear to you, or anything you are worried about, it is important that you bring up these questions. All of your questions should be answered to your satisfaction before the operation.

REMEMBER

You may change your mind any time before the operation. Make sure you do not wish to father children under any circumstances before you decide to be sterilized.

RULES FOR STERILIZATION OPERATIONS FUNDED BY THE FEDERAL GOVERNMENT

You must be at least 21 years old.

You must wait at least 30 days to have the operation after you sign the consent form.

You may, if you choose, bring someone with you when you sign the consent form.

Your consent is effective for 180 days from the date you sign the consent form.

BE SURE TO TAKE THIS PAMPHLET AND YOUR SIGNED CONSENT FORM WITH YOU

Subpart C—Abortions and Related Medical Services in Federally Assisted Programs of the Public Health Service

AUTHORITY: Sec. 118, Pub. L. 96-86, Oct. 12, 1979, unless otherwise noted.

SOURCE: 43 FR 4570, Feb. 2, 1978, unless otherwise noted.

§ 50.301 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, appropriated to the Department of Health and Human Services and administered by the Public Health Service.

§ 50.302 Definitions.

As used in this subpart: (a) "Law enforcement agency" means an agency, or any part thereof, charged under applicable law with enforcement of the general penal statutes of the United States, or of any State or local jurisdiction.

(b) "Medical procedures performed upon a victim of rape or incest" means any medical service, including an abortion, performed for the purpose of preventing or terminating a pregnancy arising out of an incident of rape or incest.

(c) "Physician" means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she practices.

(d) "Public health service" means: (1) An agency of the United States or of a State or local government, that provides health or medical services; and

(2) A "rural health clinic," as defined under section 1(d)(aa)(2) of Pub. L. 95-210, 91 Stat. 1485; except that any agency or facility whose principal function is the performance of abortions is specifically excluded from this definition.

§ 50.303 General rule.

Federal financial participation is not available for the performance of an abortion in programs or projects to which this subpart applies except under circumstances described in §§ 50.304 or 50.306.

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.304 Life of the mother would be endangered.

Federal financial participation is available in expenditures for an abor-

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tion when a physician has found, and so certified in writing to the program or project, that on the basis of his/her professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

(Sec. 101, Pub. L. 95-205, 91 Stat. 1461, Dec. 9, 1977)

[43 FR 13868, July 21, 1978]

§ 50.305 [Reserved]

§ 50.306 Rape and incest.

Federal financial participation is available in expenditures for medical procedures performed upon a victim of rape or incest if the program or project has received signed documentation from a law enforcement agency or public health service stating:

(a) That the person upon whom the medical procedure was performed was reported to have been the victim of an incident of rape or incest;

(b) The date on which the incident occurred;

(c) The date on which the report was made, which must have been within 60 days of the date on which the incident occurred;

(d) The name and address of the victim and the name and address of the person making the report (if different from the victim); and

(e) That the report included the signature of the person who reported the incident.

Federal financial participation is also available in expenditures for abortions for victims of rape or incest under the circumstances described in § 50.304 without regard to the requirements of the preceding sentence.

(Sec. 101, Pub. L. 95-205, 91 Stat. 1461, Dec. 9, 1977)

[43 FR 13868, July 21, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.307 Documentation needed by programs or projects.

Federal financial participation is unavailable for the performance of abortions or other medical procedures otherwise provided for under §§ 50.304 and 50.306 if the program or project has paid without first having received the certifications and documentation specified in those sections.

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.308 Drugs and devices and termination of ectopic pregnancies.

Federal financial participation is available with respect to the cost of drugs or devices to prevent implantation of the fertilized ovum, and for medical procedures necessary for the termination of an ectopic pregnancy.

§ 50.309 Recordkeeping requirements.

Programs or projects to which this subpart applies must maintain copies of the certifications and documentation specified in §§ 50.304 and 50.306 for three years pursuant to the retention and custodial requirements for records at 45 CFR 74.20 et seq.

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.310 Confidentiality.

Information in the records or in the possession of programs or projects which is acquired in connection with the requirements of this subpart may not be disclosed in a form which permits the identification of an individual without the individual's consent except as may be necessary for the health of the individual or as may be necessary for the Secretary to monitor the activities of those programs or projects. In any event, any disclosure shall be subject to appropriate safeguards which will minimize the likelihood of disclosures of personal information in identifiable form.

Subpart D—Public Health Service Grant Appeals Procedure

Source: 39 FR 33782, Sept. 19, 1974, unless otherwise noted.

§ 50.401 Purpose.

This subpart establishes an informal procedure for resolution of post-award grant disputes prior to their submission to the Departmental Grant Appeals Board established in 45 CFR Part 16 (38 FR 9906, April 20, 1973).

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§ 50.402 Applicability.

This subpart is applicable to all grant programs which are subject to 45 CFR Part 16 ("Department Grant Appeals Process") and which are administered by the National Institutes of Health, the Health Services Administration, the Health Resources Administration, the Center for Disease Control, the Alcohol, Drug Abuse and Mental Health Administration, or the Food and Drug Administration, or by the Public Health Service Regional Offices. For the scope of 45 CFR Part 16, see 45 CFR 16.2 and the appendices to such part.

[41 FR 49987, Nov. 12, 1976]

§ 50.403 Policy.

The Secretary of Health and Human Services has established a Departmental Grant Appeals Board for the purpose of reviewing and providing hearings upon post-award disputes which may arise in the administration of certain grant programs by constituent agencies of the Department. Section 16.5(b)(2) of the Charter (45 CFR Part 16) which establishes such Board authorizes DHHS agencies to establish informal appeal procedures which must be exhausted before a formal appeal to the Departmental Board will be allowed. Pursuant to § 16.5(b)(2) of that Charter, this document provides an informal preliminary procedure for resolution of such disputes within the Public Health Service, in order to preclude submission of cases to the Departmental Appeals Board before the Public Health Service has had an opportunity to review decisions of its officials and to settle disputes with grantees.

§ 50.404 Scope.

(a) Adverse determinations to which this procedure is applicable are as follows:

(1) Termination, in whole or in part, of a grant for failure of the grantee to carry out its approved project in accordance with the applicable law and the terms and conditions of such assistance or for failure of the grantee otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.

(2) A determination that an expenditure not allowable under the grant has been charged to the grant or that the grantee has otherwise failed to discharge its obligation to account for grant funds.

(3) The disapproval of a grantee's written request for permission to incur an expenditure during the term of a grant.

(4) A determination that a grant is void.

(b) A determination described in paragraph (a) of this section may not be reviewed by the review committee described in § 50.405 unless an officer or employee of the agency or the Regional Office has notified the grantee in writing of such determination. Such notification shall set forth the reasons for the determination in sufficient detail to enable the grantee to respond and shall inform the grantee of his opportunity for review under this subpart. In the case of a determination under paragraph (a)(3) of this section, the failure of an agency or a Regional Office to approve a grantee's request within a reasonable time, which shall be no longer than 30 days after the postmark date of the grantee's request shall be deemed by the review committee a notification for purposes of this paragraph.

(c) Prior to submission to the Departmental Grant Appeals Board of an issue covered by paragraph (a) of this section, the grantee must exhaust the procedure set forth in § 50.406 of this subpart.

§ 50.405 Review committees.

The head of each agency or his designee shall appoint review committees for reviewing appeals of adverse determinations made by Headquarters officials in his agency. For adverse determinations made by Regional Offices the Assistant Secretary for Health or his designee shall appoint review committees. A minimum of three employees shall be appointed (one of whom shall be designated as chairman) either on an ad hoc, case-by-case basis, or as regular members of review committees for such terms as may be designated. None of the members of the review committee reviewing any given appeal may be from the office of the responsible official whose determination is being appealed.

§ 50.406 Procedure.

(a) A grantee with respect to whom an adverse determination described in § 50.404(a) above has been made and who desires a review of such determination must submit a request for such review to the head of the appropriate agency or his designee (or in the case of Regional Office determinations to the Assistant Secretary for Health or his designee) no later than thirty (30) days after the written notification of such determination is received: *Provided*, That

(1) An extension of time may be granted for good cause shown, and

(2) Where the determination is one described in § 50.404(a)(3), the grantee's request for review must be postmarked no later than 90 days after the postmark date of the grantee's request for permission to incur an expenditure.

(b) Although the request for review need not follow any prescribed form, it shall contain a full statement of the grantee's position with respect to the determination being appealed and the pertinent facts and reasons in support of such position. Except in the case of a determination described in the last sentence of § 50.404(b), the grantee shall attach to this submission a copy of the notice of adverse determination.

(c) When a request for review has been filed under this subpart with respect to a determination, no action may be taken by the awarding agency or Regional Office pursuant to such determination until such request has been disposed of, except that the filing of the request shall not affect the authority which the agency or Regional Office may have to suspend assistance or otherwise to withhold or defer payments under the grant during proceedings under this subpart.

(d) Upon receipt of such a request, the head of the agency or his designee (or, if the adverse determination was made in a Regional Office, the Assistant Secretary for Health or his designee) will immediately notify the office responsible for the adverse determination.

(e) The agency or Regional Office involved will provide the review committee appointed pursuant to § 50.405 with copies of all background materials (including application, award, summary statements, and correspondence) and any additional information available.

(f) The review committee may, at its discretion, invite the grantee, the agency or Regional Office staff, or both to discuss with the review committee pertinent issues, and to submit such additional information as it deems appropriate.

(g) Based on its review, the review committee will prepare a written response to be signed by the chairman. This written response shall be sent to the grantee, with a copy to the official responsible for the adverse determination. If such response is adverse to the grantee's position, the correspondence shall state the grantee's right to appeal to the Departmental Grant Appeals Board, pursuant to 45 CFR Part 16.

Subpart E—Maximum Allowable Cost for Drugs

AUTHORITY: Secs. 215, 58 Stat. 690, as amended (42 U.S.C. 216).

SOURCE: 40 FR 34514, Aug. 15, 1975, unless otherwise noted.

§ 50.501 Applicability.

This subpart is applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service. It applies to Federal funds and to non-Federal funds which are required to be expended as a condition to receiving Federal funds under such programs or projects.

§ 50.502 Definitions.

As used in this subpart:

(a) "Public Health Service" means the Office of the Assistant Secretary for Health, Health Services Administration, Health Resources Administration, National Institutes of Health, Center for Disease Control, Alcohol, Drug Abuse and Mental Health Administration, Food and Drug Administration, and all of their constituent agencies.

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) "Program funds" means (1) Federal funds provided through grant or contract to support a program or project covered by § 50.501, and (2) any non-Federal funds that are required as a condition of such grant or contract to be expended to carry out such program or project.

(d) "Provider" means one who furnishes medical or pharmaceutical services or supplies for which program funds may be expended under any of the programs or projects described in § 50.501.

(e) "Acquisition cost" means the price generally and currently paid by providers for a drug marketed or sold by a particular formulator or labeler in the package size of drug most frequently purchased by providers, as determined by the Secretary on the basis of drug price information furnished by the Department.

§ 50.503 Policy.

It is the policy of the Secretary that program funds which are utilized for the acquisition of drugs be expended in the most economical manner feasible. In furtherance of this policy, the Secretary has established, in 45 CFR Part 19, a procedure for determining the Maximum Allowable Cost for drugs which are purchased with program funds.

§ 50.504 Allowable cost of drugs.

(a) The maximum amount which may be expended from program funds for the acquisition of any drug shall be the lowest of

(1) The maximum allowable cost (MAC) of the drug, if any, established in accordance with 45 CFR Part 19, plus a dispensing fee determined by the Secretary in accordance with paragraph (b) of this section, to be reasonable;

(2) The acquisition cost of the drug plus a dispensing fee determined by the Secretary, in accordance with paragraph (b) of this section, to be reasonable; or

(3) The provider's usual and customary charge to the public for the drug; *Provided,* That the MAC established for any drug shall not apply to a brand of that drug prescribed for a patient which the prescriber has certified, in accordance with paragraph (c) of this section, is medically necessary for that patient; *And Provided further,* That where compensation for drug dispensing is included in other costs allowable under the applicable program statute and regulations, the terms and conditions of the grant or contract, and the applicable cost principles prescribed in 45 CFR Part 74, no separate dispensing fee will be recognized.

(b) In determining whether a dispensing fee is reasonable, the Secretary will take into account:

(1) Cost components such as overhead, professional services, and profits,

(2) Payment practices of third-party payment organizations, including other Federal programs such as titles XVIII and XIX of the Social Security Act; and

(3) Any surveys by States, universities or others of costs of pharmacy operations and the fees charged in the particular area.

(c) A certification by a prescriber, pursuant to paragraph (a) of this section, that a brand of drug is medically necessary for a particular patient shall be in the prescriber's own handwriting, in such form and manner as the Secretary may prescribe. An example of an acceptable certification is the notation "brand necessary". A procedure for checking a box on a form will not constitute an acceptable certification.

PART 51b—PROJECT GRANTS FOR PREVENTIVE HEALTH SERVICES

Subpart A—General Provisions

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AUTHORITY: Secs. 317 and 318, Public Health Service Act (42 U.S.C. 247b and 247c); sec. 1743 of Pub. L. 97-35, 95 Stat. 763 (31 U.S.C. 1243 note).

SOURCE: 44 FR 40501, July 11, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 51b.101 To which programs do these regulations apply?

The regulations of this part apply to grants authorized for childhood immunization, influenza immunization, and urban rat control, and fluoridation programs under section 317 of the Public Health Service Act (42 U.S.C. 247b) and to grants authorized for venereal disease prevention and control under section 318 (42 U.S.C. 247c).

[44 FR 55379, Sept. 26, 1979]

§ 51b.102 Definitions.

As used in these regulations:

"Act" means the Public Health Service Act, as amended.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department to whom the authority involved has been delegated.

"State" means one of the 50 States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

§ 51b.103 What are the general application requirements?

(a) Application forms and instructions for their preparation and submission may be obtained from the PHS Regional Health Administrator of the Department of Health and Human Services for the region in which a program is to be conducted. The application shall contain a full description of the program objectives, plans, and activities.

(b) The application shall be signed by an individual authorized by the applicant to assume the obligations imposed by these regulations and any additional conditions of the grant.

(c) The application shall contain evidence satisfactory to the Secretary that it has been submitted for appropriate action to the planning agency designated by the Secretary under Title XV of the Act.

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§ 51b.104 How will grant payments be made under a grant award?

(a) The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award. These payments may be made either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the program. The payments shall be made as the Secretary determines necessary to promote prompt initiation and advancement of the approved program.

(b) The Secretary may reduce the payment under a grant by the amount of the fair market value of any supplies (including vaccines and other preventive agents) or equipment furnished a grant recipient, when it is furnished at the request of the recipient. The Secretary also may reduce the payment under a grant by the amount of the pay, allowances, travel expenses, and any other costs in connection with the detail of any officer or employee of the Government to the recipient, when the detail is at the request of the recipient. The amount the grant is reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the official, and shall, for the purpose of these regulations, be deemed to have been paid to the recipient.

§ 51b.105 Which other HHS regulations apply to these grants?

Several other HHS regulations apply to grants under this part. These include:

45 CFR Part 74—Administration of Grants

45 CFR Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 84—Nondiscrimination on the Basis of Handicap in Federally Assisted Programs and Activities Receiving or Benefitting from Federal Financial Assistance

§ 51b.106 What other conditions apply to these grants?

The Secretary may impose additional conditions, including conditions governing the use of information or consent forms, when they are necessary to advance the approved program, the interest of the public health, or the conservation of grant funds.

§ 51b.107 Is participation in grant programs voluntary?

Nothing in these regulations shall be construed to require any State or any political subdivision of a State to have a preventive health service program which would require any person who objects to treatment to be treated under the program.

Subpart B—Grants for Childhood Immunization Programs

§ 51b.201 To which programs does this subpart apply?

The regulations in this subpart apply to the award of grants under Section 317 of the Act for programs to immunize children against vaccine preventable diseases.

§ 51b.202 Definitions.

As used in this subpart:

"Childhood immunization program" means a preventive health service program to immunize children against vaccine preventable diseases including poliomyelitis, measles, mumps, rubella, diphtheria, pertussis, and tetanus.

§ 51b.203 Who is eligible for a grant under this subpart?

An applicant must be a State agency or an agency of a political subdivision of a State which has legal responsibility for disease control under the laws of a State.

§ 51b.204 What information is required in the application?

The application for a grant must include a description of the following:

(a) The nature and extent of the disease problem in the area.

(b) The need for grant support.

(c) The specific objectives and priorities of the program.

(d) Current immunization programs and the additional or intensified activities to be carried out to meet the objectives and priorities. The following program elements must be included and described:

(1) Surveillance of the vaccine preventable diseases included in the definition of childhood immunization program.

(2) Systematic identification of unimmunized or inadequately immunized population groups.

(3) Systematic identification and delivery of services to inadequately immunized population groups as they are identified, assuring that no one will be denied services because of inability to pay and that the services are provided in a manner which preserves human dignity and maximizes acceptance.

(4) Techniques and procedures for controlling outbreaks of disease.

(5) Professional and public awareness activities, with emphasis on underimmunized populations.

(6) Use of public and nonprofit private entities and volunteers.

(7) Continuation of activities to maintain high immunization levels.

(8) Coordination of activities with other related Federally assisted programs.

(e) The manner in which the applicant intends to conduct and evaluate the project including the working relationship of the applicant with private health care providers, other public health care agencies, and voluntary organizations in the area to be served.

(f) Studies, if any, to identify and develop new methods of controlling diseases listed in § 51b.202.

(g) A budget and justification for the grant funds requested.

(h) Other information which supports the requests for funds.

§ 51b.205 How will grant applications be evaluated and the grants awarded?

(a) Within the limits of funds available, the Secretary may award a grant to assist in meeting part of the cost of a childhood immunization program. Grants will be awarded to those applicants whose projects he determines will best promote the purposes of Section 317 of the Act. Before awarding a grant to a local public entity of a State, the Secretary will consult with the State health authority.

(b) Priorities for funding will be based on the following factors:

(1) The relative extent of the problems which are caused by one or more of the vaccine preventable diseases in the area served by the applicant.

(2) The extent to which the proposed program is designed to eliminate or reduce the problems.

(3) The extent to which the proposed program will increase the immunization rates in population groups identified as having the lowest immunity levels.

(4) The extent to which the grantee will cooperate with and use public and nonprofit private entities and volunteers.

(5) The extent to which a strong commitment to the objectives of the program is reflected in the commitment of grantee resources to the program.

(c) The approval of a grant application or the award of funds shall not obligate the United States to make additional, supplemental, continuation, or other award to any approved program. The grantee must apply separately for continuing support.

§ 51b.206 How can grant funds be used?

Grant funds awarded under this subpart may be used to purchase supplies, materials, and equipment for childhood immunization programs. Grant funds also may be used to pay for salaries or wages and related expenses for personnel directly involved in the planning, organization, promotion, epidemiology, surveillance, and other program activities.

Subpart C—[Reserved]

Subpart D—Grants for Venereal Disease Control Programs

§ 51b.401 To which programs does this subpart apply?

The regulations in this subpart apply to the award of project grants under section 318(c) of the Act for venereal disease control programs.

§ 51b.402 Definitions.

As used in this subpart:

"Venereal disease" means gonorrhea, syphilis, or any other disease which can be sexually transmitted and which the Secretary determines is or may be amenable to control with assistance provided under this authority and which is of national significance.

"Venereal disease control program" means a program designed primarily to carry out activities or to provide services to systematically detect and prevent venereal diseases as compared to those activities or services which are designed primarily for the purpose of diagnosing or treating venereal disease patients or suspects.

§ 51b.403 Who is eligible for a grant under this subpart?

An applicant must be a State agency or an agency of a political subdivision of a State which has legal responsibility for disease control under the laws of a State.

§ 51b.404 What are the confidentiality requirements?

All information obtained by program personnel related to the examination, care, and treatment of a participant in this program shall be held confidential. It shall not be divulged without the individual's consent except as may be required by the law of a State or political subdivision of a State or as may be necessary to provide services to the individual. Information may be disclosed in summary, statistical, or other form, or for clinical or reseach purposes, but only if the disclosure does not identify particular individuals.

§ 51b.405 What information is required in the application?

(a) The application must include a description of the following:

(1) The nature and extent of the venereal disease problem in the area.

(2) The need for grant support.

(3) The immediate and long-range objectives of the project in specific and measurable terms.

(4) The activities to be carried out to meet the objectives.

The following program elements must be included and described:

(i) Venereal disease surveillance.

(ii) Casefinding and case followup.

(iii) Interstate epidemiologic referral and followup.

(iv) Professional and public venereal disease education.

(5) At the option of the applicant, special studies or demonstrations to evaluate or test venereal disease prevention and control strategies and activities.

(6) The manner in which the applicant intends to conduct and evaluate the project, including a system for analysis of morbidity data so that control activities can be efficiently evaluated and targeted.

(7) The present venereal disease control program and the environment in which the proposed program will function, including:

(i) The working relationship of the applicant to private health providers, public health care agencies, and voluntary organizations in the area to be served.

(ii) Actions which will be taken to develop, promote, and enforce appropriate laws and regulations facilitating venereal disease control.

(iii) A description of the diagnostic and treatment services that will be provided.

(8) A budget and justification for the grant funds requested.

(9) Assurances that no one will be denied services because of inability to pay, and that the services are provided in a manner which preserves human dignity and maximizes acceptance.

(10) Other information which supports the request for funds.

(b) When efforts are made to collect payment for services supported in whole or in part from a third party, a rate schedule for third party charges must be submitted with the application and approved as part of the program plan. Under no circumstances may a billing arrangement be made which jeopardizes the confidentiality of patient records.

§ 51b.406 How will grant applications be evaluated and the grants awarded?

(a) Within the limits of funds available, the Secretary may award a grant to assist in meeting the cost of a venereal disease control program. Grants will be awarded to those applicants whose programs the Secretary determines will best promote the purposes of Section 318 of the Act. Before awarding a grant to a political subdivision of a State the Secretary will consult with the State health authority. Priorities for funding will be based on the following factors:

(1) The relative extent of the venereal disease problem in the area served by the applicant.

(2) The design of the venereal disease prevention and control program.

(3) The general quality of the applicant's plan of operation and objectives in accordance with the requirements in this regulation and the extent to which the project renders services to groups having the highest incidence of venereal disease.

(4) The capacity of the applicant to make effective use of Federal funds.

(5) The commitment of the applicant to the control of venereal disease as reflected in the commitment of applicant resources to the program.

(b) The approval of a grant application or the award of funds shall not obligate the United States to make additional, supplemental, continuation, or other award to any approved project. The grantee must apply separately for continuing support.

§ 51b.407 How can grant funds be used?

Grant funds awarded under this subpart may be used only for programs approved under section 318(c) of the Act. Unless specifically approved for that purpose, grant funds shall not be used for performing diagnostic tests (other than gonorrhea screening tests), maintaining central registries, providing diagnostic and treatment facilities and services, or automatic data processing. To obtain special approval, the grantee shall justify the exception to the satisfaction of the Secretary that funds for this purpose are necessary for the proper conduct of the program and are otherwise unavailable. Exceptions will be limited to (a) special studies or demonstrations, (b) the support of developmental or start-up activity, or (c) the support of an essential service which will result in a saving to a detection or prevention activity supported by the grant. Unless otherwise approved, exceptions based on paragraphs (b) and (c) of this section are only allowed during one funding period. The grantee must assure support of these activities in subsequent funding periods.

Subpart E—Grants for Influenza Immunization Programs

§ 51b.501 To which programs does this subpart apply?

The regulations in this subpart apply to the award of grants under section 317 of the Act for programs to immunize persons in high-risk groups against influenza.

§ 51b.502 Definitions.

As used in this subpart:

"High-risk groups" means those groups of persons at highest risk of serious illness or death due to influenza and its complications, as specified in grant guidelines.

§ 51b.503 Who is eligible for a grant under this subpart?

An applicant must be a State agency or an agency of a political subdivision of a State which has legal responsibility for disease control under the laws of a State.

§ 51b.504 What information is required in the application?

The application for a grant must include a description of the following:

(a) Background and need for grant support including:

(1) An overview of the public, private, and voluntary health care delivery systems in the project area which are or will be available to conduct the program.

(2) The extent of current influenza immunization services provided in the public and private sectors with specific information concerning the purchase, distribution, use of vaccine, and the populations served.

(3) Estimates of the number of persons in the high-risk groups.

(b) Long-term and short-term objectives which are specific, measurable, and realistic, and which relate to the National Program Goals, as specified in grant guidelines.

(c) A detailed description of the method for carrying out the following program activities:

(1) Delivery of influenza vaccinations to high-risk populations, through cooperative efforts with public health and private health care providers and voluntary organizations serving high-risk groups.

(2) Detecting and reporting outbreaks of influenza, including laboratory and epidemiologic surveillance.

(3) Monitoring illnesses or injuries which occur subsequent to vaccination.

(4) Dissemination of influenza information to health care providers and high-risk individuals to create awareness of the need for vaccination and to encourage active participation in the program.

(5) Assuring accountability for all vaccines stored, distributed, and administered.

(6) Other activities which will promote the achievement of program objectives.

(d) A budget and justification for grant funds requested.

(e) Assurance that no one will be denied services because of inability to pay and that the services are provided in a manner which preserves human dignity and maximizes acceptance.

§ 51b.505 How will grant applications be evaluated and the grants awarded?

(a) Within the limits of funds available, the Secretary may award grants to assist in meeting part of the cost of an influenza immunization program. Before awarding a grant to a political subdivision of a State, the Secretary will consult with the State health authority.

(b) Priorities for funding will be based on the extent to which:

(1) The proposed activities are likely to result in a balanced program of vaccine delivery, detection and reporting of influenza outbreaks, monitoring of vaccine reactions, and information dissemination to health care providers and high-risk individuals.

(2) The plan of operation is likely to supplement rather than replace vaccinations given in the public or private sector.

(3) Project objectives are specific, measurable, realistic, and related to the national program goals.

(4) Budget requests and the proposed use of grant funds are appropriate and reasonable for a balanced program.

(5) There are plans for the coordination of activities with related programs and the effective use of volunteer groups and other community resources.

(6) The described methods of evaluation are likely to be effective in measuring the achievement of program objectives.

(c) The approval of a grant application or the award of funds shall not obligate the United States to make supplemental, continuation, or other award to a grantee. The grantee must apply separately for continuing support.

§ 51b.506 How can grant funds be used?

(a) Grant funds may be used for costs of planning and establishing influenza immunization delivery services, for the purchase of influenza vaccine, and for the implementation of other approved program activities.

(b) Vaccine purchased with grant funds may be provided to private practitioners who agree not to charge for the vaccine, although a charge for vaccine administration may be permitted.

PART 51c—GRANTS FOR COMMUNITY HEALTH SERVICES

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AUTHORITY: Sec. 330, Public Health Service Act, 89 Stat. 342, (42 U.S.C. 254c); Sec. 215, Public Health Service Act, 58 Stat. 690, (42 U.S.C. 216).

SOURCE: 41 FR 53205, Dec. 3, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 51c.101 Applicability.

The regulations of this subpart are applicable to all project grants authorized by section 330 of the Public Health Service Act (42 U.S.C. 254c).

§ 51c.102 Definitions.

As used in this part:

(a) "Act" means the Public Health Service Act.

(b) "Catchment area" means the area served by a project funded under section 330 of the Act.

(c)(1) "Community health center" or "center" means an entity which, through its staff and supporting resources or through contracts or cooperative arrangements with other public or private entities, provides for all residents of its catchment area:

(i) Primary health services;

(ii) As determined by the Secretary to be appropriate for particular centers, supplemental health services necessary for the adequate support of primary health services;

(iii) Referral to providers of supplemental health services and payment, as determined by the Secretary to be appropriate and feasible, for their provision of such services;

(iv) Environmental health services, as determined by the Secretary to be appropriate for particular centers; and

(v) Information on the availability and proper use of health services.

(2) For purposes of paragraph (c)(1) of this section, the provision of a given service by a center will be determined by the Secretary to be appropriate where:

(i) There is a need, as determined by the Secretary, for the provision of such service in the catchment area; and

(ii) The provision of such service by the center is feasible, taking into consideration the center's projected revenues, other resources, and grant support under this part.

(d) "Environmental health services" means the detection and alleviation of unhealthful conditions of the environment of the catchment area, such as problems associated with water supply, sewage treatment, solid waste disposal, rodent and parasite infestation, and housing conditions. For the purposes of this part, the detection and alleviation of unhealthful conditions of the environment includes the notification of and making of arrangements with appropriate Federal, State, or local authorities responsible for correcting such conditions.

(e) "Medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services. Medically underserved areas will be designated by the Secretary and a list of those designated will be published in the FEDERAL REGISTER from time to time, taking into consideration the following factors, among others:

(1) Available health resources in relation to size of the area and its population, including appropriate ratios of primary care physicians in general or family practice, internal medicine, pe-

diatrics, or obstetrics and gynecology to population;

(2) Health indices for the population of the area, such as infant mortality rate;

(3) Economic factors affecting the population's access to health services, such as percentage of the population with incomes below the poverty level; and

(4) Demographic factors affecting the population's need and demand for health services, such as percentage of the population age 65 and over.

(f) "Nonprofit," as applied to any private agency, institution, or organization, means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(g) "Physician" means a licensed doctor of medicine or doctor of osteopathy.

(h) "Primary health services" means:

(1) Diagnostic, treatment, consultative, referral, and other services rendered by physicians, and, where feasible, by physician's extenders, such as physicians' assistants, nurse clinicians, and nurse practitioners;

(2) Diagnostic laboratory services and diagnostic radiologic services;

(3) Preventive health services, including medical social services, nutritional assessment and referral, preventive health education, children's eye and ear examinations, prenatal and post-partum care, prenatal services, well child care (including periodic screening), immunizations, and voluntary family planning services;

(4) Emergency medical services, including provision, through clearly defined arrangements, for access of users of the center to health care for medical emergencies during and after the center's regularly scheduled hours;

(5) Transportation services as needed for adequate patient care, sufficient so that residents of the catchment area served by the center with special difficulties of access to services provided by the center receive such services; and

(6) Preventive dental services provided by a licensed dentist or other qualified personnel, including (i) oral hygiene instruction; (ii) oral prophylaxis, as necessary; and (iii) topical application of fluorides, and the prescription of fluorides for systemic use when not available in the community water supply.

(i) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(j) "Supplemental health services" means health services which are not included as primary health services and which are:

(1) Inpatient and outpatient hospital services;

(2) Home health services;

(3) Extended care facility services;

(4) Rehabilitative services (including physical and occupational therapy) and long-term physical medicine;

(5) Mental health services, including services of psychiatrists, psychologists, and other appropriate mental health professionals;

(6) Dental services other than those provided as primary health services;

(7) Vision services, including routine eye and vision examinations and provision of eyeglasses, as appropriate and feasible;

(8) Allied health services;

(9) Pharmaceutical services, including the provision of prescription drugs;

(10) Therapeutic radiologic services;

(11) Public health services (including nutrition education and social services);

(12) Ambulatory surgical services;

(13) Health education services; and

(14) Services, including the services of outreach workers, which promote and facilitate optimal use of primary health services and services referred to in the preceding subparagraphs of this paragraph and, if a substantial number of individuals in the population served by the center are of limited English-speaking ability, the services of outreach workers and other personnel fluent in the language or languages spoken by such individuals.

§ 51c.103 Eligibility.

Any public or nonprofit private entity is eligible to apply for a grant under this part.

§ 51c.104 Application.

(a) An application for a grant under this part shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.

(b) The application shall contain a budget and narrative plan of the manner in which the applicant intends to conduct the project and carry out the requirements of this part. The application must describe how and the extent to which the project has met, or plans to meet, each of the requirements in Subpart B (relating to grants for planning and developing community health centers), Subpart C (relating to grants for the operation of community health centers), or Subpart D (relating to grants for the operation of community health projects), as applicable. In addition, applications must include:

(1) A statement of specific, measurable objectives and the methods to be used to assess the achievement of the objectives in specified time periods and at least on an annual basis.

(2) The precise boundaries of the catchment area to be served by the applicant, including an identification of the medically underserved population or populations within the catchment area. In addition, the application shall include information sufficient to enable the Secretary to determine that the applicant's catchment area meets the following criteria:

(i) The size of such area is such that the services to be provided by the applicant are available and accessible to the residents of the area promptly and as appropriate;

(ii) The boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and areas served by Federal and State health and social service programs; and

(iii) The boundaries of such area eliminate, to the extent possible, barriers resulting from the area's physical characteristics, its residential patterns, its economic and social groupings, and available transportation.

(3) The results of an assessment of the need that the population served or proposed to be served has for the services to be provided by the project (or in the case of applications for planning and development projects, the methods to be used in assessing such need), utilizing, but not limited to, the factors set forth in § 51c.102(e)(1)-(4).

(4) Position descriptions for key personnel who will be utilized in carrying out the activities of the project and a statement indicating the need for the positions to be supported with grant funds to accomplish the objectives of the project.

(5) Letters and other forms of evidence showing that efforts have been made to secure financial and professional assistance and support for the project within the proposed catchment area and the continuing involvement of the community in the development and operation of the project.

(6) An assurance that an independent certified public accountant, or a public accountant licensed before December 31, 1970, will be engaged to certify that the system for the management and control of its financial assets will be in accord with sound financial management practices, including applicable Federal requirements.

(7) A list of all services proposed to be provided by the project.

(8) A list of services which are to be provided directly by the project through its own staff and resources and a description of any contractual or other arrangements (including copies of documents, where available) entered into, or planned for the provision of services.

(9) The schedule of fees and/or payments and schedule of discounts for services provided by the project.

(10) Evidence that:

(i) The requirements of Part I of Office of Management and Budget Circular No. A-95 have been satisfied, and

(ii) All applicable requirements for review and/or approval of the application under Title XV of the Act have been met.

(11) An assurance that the project will be conducted in accordance with

the applicable requirements of this part.

(c) The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the applicable regulations of this part, and any additional conditions of the grant.

§ 51c.105 Accord with health planning.

A grant may be made under this part only if the applicable requirements of title XV of the Act relating to review and approval by the appropriate health planning agencies have been met.

§ 51c.106 Amount of grant.

(a) The amount of any award under this part will be determined by the Secretary on the basis of his estimate of the sum necessary for a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary: *Provided, however,* That no grant shall be made for an amount in excess of the total cost found necessary by the Secretary to carry out the project.

(i) In determining the percentage of project costs to be borne by the grantee, factors which the Secretary will take into consideration will include the following:

(A) The ability of the grantee to finance its share of project costs from non-Federal sources;

(B) The need in the area served by the project for the services to be provided; and

(C) The extent to which the project will provide services in an innovative manner which the Secretary desires to stimulate in the interest of developing more effective health service delivery systems on a regional or national basis.

(ii) At any time after approval of an application under this part, the Secretary may retroactively agree to a percentage of project costs to be borne by the grantee lower than that determined pursuant to paragraph (a)(2)(i) of this section where he finds that changed circumstances justify a smaller contribution.

(iii) In determining the grantee's share of project costs, costs borne by Federal grant funds, or costs used to match other Federal grants, may not be included except as otherwise provided by law or regulations.

(b) All grant awards shall be in writing, and shall set forth the amount of funds granted and the period for which support is recommended.

(c) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application.

§ 51c.107 Use of project funds.

(a) Any funds granted pursuant to this part, as well as other funds to be used in performance of the approved project, may be expended solely for carrying out the approved project in accordance with section 330 of the Act, the applicable regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

(b) Project funds awarded under this part may be used for, but need not be limited to, the following:

(1) The costs of acquiring and modernizing existing buildings (including the costs of amortizing the principal of, and paying interest on, loans), but

only in accordance with subpart E of this part and as approved in the grant award;

(2) The costs of obtaining technical assistance to develop and improve the management capability of the project, but only as approved by the Secretary;

(3) The reimbursement of members of the grantee's governing board, if any, for reasonable expenses actually incurred by reason of their participation in board activities;

(4) The reimbursement of governing board members for wages lost by reason of participation in the activities of such board if the member is from a family with an annual family income below $10,000 or if the member is a single person with an annual income below $7,000;

(5) The cost of delivering health services, including services rendered on a prepaid capitation basis, to residents of the project's catchment area within the following limitations: grant funds may be used to pay the full cost of project services to individuals and families with annual incomes at or below those set forth in the most recent "CSA Income Poverty Guidelines" (45 CFR 1060.2) issued by the Community Services Administration; and to pay the portion of the cost of services provided in accordance with the schedule of discounts which, under such schedule, is uncompensated; *Provided*, That (i) charges will be made to such individuals and families in accordance with § 51c.303(f) of Subpart C; (ii) reasonable effort shall be made to collect such charges under a billing and collections system; and (iii) the charge to grant funds shall exclude any amounts collected pursuant to paragraph (b)(5)(ii) of this section;

(6) The cost of insurance for medical emergency and out-of-area coverage;

(7) The cost of providing to the staff of the project training related to the provision of health services provided or to be provided by the project, and, to the staff and governing board, if any, training related to the management of an ambulatory care facility, consistent with the applicable requirements of 45 CFR Part 74; and

(8) The cost of developing and maintaining a reserve fund where required by State law for prepaid health care plans.

(c) Prior approval by the Secretary of revisions of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

§ 51c.108 Grant payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred, to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 51c.109 Nondiscrimination.

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, (42 U.S.C. 2000d et seq.)) and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of race, color, or national origin be excluded from participation, in be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal Financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR Part 80). In addition, no person shall, on the grounds of age, sex, creed, or marital status (unless otherwise medically indicated), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity so receiving Federal financial assistance.

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

§ 51c.110 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about recipients of services shall be held confidential, and shall not be divulged without the individual's consent except as may be required by law or as may be necessary to provide service to the individual or to provide for medical audits by the Secretary or his designee with appropriate safeguards for confidentiality of patient records. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 51c.111 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 51c.112 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project, the grantee shall account for the sum total of all amounts paid as well as other funds and in-kind contributions by presenting or otherwise making available evidence satisfactory to the Secretary of expenditure for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for interest earned on grant funds.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the government of the political subdivisions of the State. All grantees other than a State, as defined, must return all interest earned on grant funds to the Federal Government.

(c) *Grant closeout*— (1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (b) of this section;

(iii) Any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74.

§ 51c.113 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part to State and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to all other grantee organizations under this part:

45 CFR PART 74

Subpart	
A	General.
B	Cash depositories.
C	Bonding and insurance.

Subpart
D Retention and custodial requirements for records.
F Grant-related income.
G Matching and cost sharing.
K Grant payment requirements.
L Budget revision procedures.
M Grant closeout, suspension, and termination.
O Property.
Q Cost principles.

Subpart B—Grants for Planning and Developing Community Health Centers

§ 51c.201 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A of this part, are applicable to grants awarded pursuant to section 330(c) of the Act for projects for planning and developing community health centers which will serve medically underserved populations.

§ 51c.202 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 51c.104 of Subpart A, contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of § 51c.203.

§ 51c.203 Project elements.

A project for the planning and developing of a community health center supported under this subpart must:

(a) Prepare an assessment of the need of the population proposed to be served by the community health center for the services set forth in § 51c.102(c)(1) of Subpart A, with special attention to the need of the medically underserved population for such services. Such assessment of need shall, at a minimum, consider the factors listed in § 51c.102(e)(1)–(4).

(b) Design a community health center program for such population, based on such assessment, which indicates in detail how the proposed community health center will fulfill the needs identified in the assessment prepared pursuant to paragraph (a) of this section and how it will meet the requirements contained in Subpart C of this part.

(c) Develop a plan for the implementation of the program designed pursuant to paragraph (b) of this section. Such implementation plan shall provide for the time-phased recruitment and training of the personnel essential for the operation of a community health center and the gradual assumption of operational status of the project so that the project will, in the judgment of the Secretary, meet the requirements contained in Subpart C of this part as of the end of the project period.

(d) Implement the plan developed pursuant to paragraph (c) of this section in accordance with such paragraph.

(e) Make efforts to secure, within the proposed catchment area of such center to the extent possible, financial and professional assistance and support for the project.

(f) Initiate and encourage continuing community involvement in the development and operation of the project.

(g) Establish standards and qualifications for personnel (including the project director).

(h) Utilize, to the maximum extent feasible, other Federal, State, local, and private resources available for support of the project, prior to use of project funds under this subpart.

§ 51c.204 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 330(c) of the Act and the applicable regulations of this part, taking into account:

(1) The degree to which the proposed project satisfactorily provides for the elements set forth in § 51c.203;

(2) The relative need of the population to be served for the services to be provided;

(3) The administrative and management capability of the applicant;

(4) The potential of the project for development of new and effective

methods for health services delivery and management;

(5) The soundness of the fiscal plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(6) The extent to which community resources will be utilized in the project;

(7) The extent to which grants approved under this part will provide for an appropriate distribution of resources throughout the country, taking into consideration the following factors;

(i) The urban-rural area to be served;

(ii) The nature of the organization applying; and

(iii) The organizational structure for delivery of services;

(8) Whether the project's catchment area is exclusive of the area served by a community health center;

(9) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other Federally assisted health services or reimbursement programs or projects.

(b) The Secretary may:

(1) Make no more than two grants under this subpart for the same project.

(2) Make a grant under this subpart to an entity which has been awarded one or more grants under section 330(d)(1)(A) and/or section 330(d)(1)(B) of the Act only if the grant under this subpart is for a new project.

Subpart C—Grants for Operating Community Health Centers

§ 51c.301 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A, are applicable to grants awarded pursuant to section 330(d)(1)(A) of the Act for the costs of operation of community health centers which serve medically underserved populations.

§ 51c.302 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 51c.104 of Subpart A,

(a) Be submitted by an entity which may be a co-applicant which the Secretary determines is a community health center, and

(b) Contain information sufficient to enable the Secretary to determine that the center will meet the requirements of § 51c.103.

[41 FR 53205, Dec. 3, 1976, as amended at 42 FR 60418, Nov. 25, 1977]

§ 51c.303 Project elements.

A community health center supported under this subpart must:

(a) Provide the health services of the center so that such services are available and accessible promptly, as appropriate, and in a manner which will assure continuity of service to the residents of the center's catchment area.

(b) Implement a system for maintaining the confidentiality of patient records in accordance with the requirements of § 51c.110 of Subpart A.

(c) Have an ongoing quality assurance program which provides for the following:

(1) Organizational arrangements, including a focus of responsibility, to support the quality assurance program and the provision of high quality patient care;

(2) Periodic assessment of the appropriateness of the utilization of services and the quality of services provided or proposed to be provided to individuals served by the center. Such assessments shall:

(i) Be conducted by physicians or by other licensed health professionals under the supervision of physicians;

(ii) Be based on the systematic collection and evaluation of patient records; and

(iii) Identify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated.

(d) Develop management and control systems which are in accordance with sound financial management procedures, including the provision for an audit on an annual basis (unless waived for cause by the Secretary) by an independent certified public accountant or a public accountant licensed prior to December 31, 1970, to determine, at a minimum, the fiscal integrity of grant financial transactions and reports, and compliance with the regulations of this part and the terms and conditions of the grant.

(e) Where the cost of care and services furnished by or through the project is to be reimbursed under Title XIX or Title XX of the Social Security Act, obtain or make every reasonable effort to obtain a written agreement with the Title XIX or Title XX State agency for such reimbursement.

(f) Have prepared a schedule of fees or payments for the provision of its services designed to cover its reasonable costs of operation and a corresponding schedule of discounts adjusted on the basis of the patient's ability to pay. *Provided,* That such schedule of discounts shall provide for a full discount to individuals and families with annual incomes at or below those set forth in the most recent CSA Proverty Income Guidelines (45 CFR 1060.2) and for no discount to individuals and families with annual incomes greater than twice those set forth in such Guidelines, except that nominal fees for services may be collected from individuals with annual incomes at or below such levels where imposition of such fees is consistent with project goals.

(g) Make every reasonable effort, including the establishment of systems for eligibility determination, billing, and collection, to:

(1) Collect reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under Title XVIII of the Social Security Act, to medical assistance under a State plan approved under Title XIX of such Act, to social services and family planning under Title XX of such Act, or to assistance for medical expenses under any other public assistance program, grant program, or private health insurance or benefit program on the basis of the schedule of fees prepared pursuant to paragraph (f) of this section without application of any discounts, and

(2) Secure from patients payments for services in accordance with the schedule of fees and discounts required by paragraph (f) of this section.

(h) Have a governing board which meets the requirements of § 51c.304.

(i) Have developed an overall plan and budget for the center that:

(1) Provides for an annual operating budget and a three-year financial management plan which include all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items;

(2) Provides for a capital expenditures plan for at least a three-year period (including the year to which the operating budget described in paragraph (i)(1) of this section is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objective of, each anticipated expenditure in excess of $100,000 related to the acquisition of land, the improvement of land, buildings, and equipment and the replacement, modernization and expansion of buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(3) Provides for plan review and updating at least annually; and

(4) Is prepared under the direction of the governing board, by a committee consisting of representatives of the governing board, and administrative staff, and the medical staff, if any, of the center.

(j) Establish basic statistical data, cost accounting, management information, and reporting or monitoring systems which shall enable the center to provide such statistics and other information as the Secretary may reasonably require relating to the center's costs of operation, patterns of utilization of services, and the availability, accessibility, and acceptability of its services and to make such reports to the Secretary in a timely manner with such frequency as the Secretary may reasonably require.

(k) Review its catchment area annually to insure that the criteria set out in § 51c.104(b)(2) of Subpart A are met and, where such criteria are not met, revise its catchment area, with the approval of the Secretary, to conform to such criteria to the extent feasible.

(l) In the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, have developed a plan and made arrangements responsive to the needs of such populations for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and have identified an individual on its staff who is fluent in both that language and in English and whose responsibilities include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences. If more than one non-English language is spoken by such group or groups, an individual or individuals fluent in those languages and English shall be so identified.

(m) Be operated in a manner calculated to preserve human dignity and to maximize acceptability and effective utilization of services.

(n) To the extent possible, coordinate and integrate project activities with the activities of other Federally funded, as well as State and local, health services delivery projects and programs serving the same population.

(o) Establish means for evaluating progress toward the achievement of the specific objectives of the project.

(p) Provide sufficient staff, qualified by training and experience, to carry out the activities of the center.

(q) Assure that facilities utilized in the performance of the project meet applicable fire and life safety codes.

(r) Utilize, to the maximum extent feasible, other Federal, State, and local, and private resources available for support of the project, prior to use of project funds under this part.

(s) Provide for community participation through, for example, contributions of cash or services, loans of full- or part-time staff, equipment, space, materials, or facilities.

(t) Where the center will provide services through contract or other cooperative arrangements with other providers of services, establish rates and methods of payment for health care. Such payments must be made pursuant to agreements, with a schedule of rates and payment procedures maintained by the project. The project must be prepared to substantiate that such rates are reasonable and necessary.

(u) Operate in a manner such that no person shall be denied service by reason of his inability to pay therefor: *Provided, however,* That a charge for the provision of services will be made to the extent that a third party (including a Government agency) is authorized or is under legal obligation to pay such charges.

(v) In addition to the above, projects which are supported with grant funds for the operation of a prepaid health care plan also must provide:

(1) A marketing and enrollment plan, including market analysis, marketing strategy, and enrollment growth projections.

(2) A plan that provides for funding on a capitation basis of such portion of the residents of the catchment area of the center, as the Secretary shall determine.

(3) An assurance that services shall be available to all residents of the catchment area without regard to method of payment or health status.

§ 51c.304 Governing board.

A governing board for the center shall be established by an applicant as follows:

(a) *Size.* The board shall consist of at least 9 but not more than 25 members, except that this requirement may be waived by the Secretary for good cause shown.

(b) *Composition.* (1) A majority of the board members shall be individuals who are or will be served by the center and who, as a group, represent the individuals being or to be served in terms of demographic factors, such as race, ethnicity, sex.

(2) No more than one-half of the remaining members of the board may be individuals who derive more than 10 percent of their annual income from the health care industry.

(3) The remaining members of the board shall be representative of the community in which the center's catchment area is located and shall be selected for their expertise in community affairs, local government, finance

and banking, legal affairs, trade unions, and other commercial and industrial concerns, or social service agencies within the community.

(4) No member of the board shall be an employee of the center, or spouse or child, parent, brother or sister by blood or marriage of such an employee. The project director may be a nonvoting, ex-officio member of the board.

(c) *Selection of members.* The method of selection of all governing board members shall be prescribed in the by-laws or other internal governing rules of the center. Such by-laws or other rules must specify a process of selection of individuals on the governing board who represent the population served or to be served by the center so that such individuals, as a group, are representative of such population. Such process of selection in the by-laws or other rules is subject to approval by the Secretary.

(d) *Functions and responsibilities.* (1) The governing board for the center shall have authority for the establishment of policy in the conduct of the center.

(2) The governing board shall hold regularly scheduled meetings, at least once each month, for which minutes shall be kept.

(3) The governing board shall have specific responsibility for:

(i) Approval for the selection and dismissal of a project director or chief executive officer of the center;

(ii) Establishing personnel policies and procedures, including selection and dismissal procedures, salary and benefit scales, employee grievance procedures, and equal opportunity practices;

(iii) Adopting policy for financial management practices, including a system to assure accountability for center resources, approval of the annual project budget, center priorities, eligibility for services including criteria for partial payment schedules, and long-range financial planning;

(iv) Evaluating center activities including services utilization patterns, productivity of the center, patient satisfaction, achievement of project objectives, and development of a process for hearing and resolving patient grievances;

(v) Assuring that the center is operated in compliance with applicable Federal, State, and local laws and regulations; and

(vi) Adopting health care policies including scope and availability of services, location and hours of services, and quality-of-care audit procedures.

§ 51c.305 Grant evaluation and award.

Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 330(d)(1)(A) of the Act and the applicable regulations of this part, taking into consideration;

(a) The extent to which the project would provide for the elements set forth in § 51c.303;

(b) The relative need of the population to be served for the services to be provided;

(c) The potential of the center for the development of new and effective methods for health services delivery and management;

(d) The soundness of the fiscal plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(e) The administrative and management capability of the applicant;

(f) The extent to which grants approved under this part will provide for an appropriate distribution of resources throughout the country, taking into consideration the following factors:

(1) The urban-rural area to be served;

(2) The nature of the organization applying;

(3) The organizational structure for delivery of services;

(g) The number of users of the center and the level of utilization of services in previous operational periods, if any;

(h) Whether the center's catchment area is exclusive of the area served by another center;

(i) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other Federally assisted health services or reimbursement programs or projects;

(j) The extent to which community resources will be utilized by the project;

(k) The extent to which the center will provide preventive health services so as to maintain and improve the health status of the population served; and

(l) The extent to which center operations will emphasize direct health services, efficiency of operations and sound financial management.

Subpart D—Grants for Operating Community Health Projects

§ 51c.401 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A are applicable to grants awarded pursuant to section 330(d)(1)(B) of the Act for the costs of operation of projects which provide health services to medically underserved populations.

§ 51c.402 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 51c.104 of Subpart A, contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of § 51c.403 of this subpart.

§ 51c.403 Project elements.

A project for the operation of a community health project supported under this subpart must:

(a) Meet all of the requirements of § 51c.303 of this part except for paragraph (h).

(b) Provide those services enumerated in § 51c.102(c)(1) of this part which the Secretary determines to be feasible and desirable and which are specified in the grant award.

(c) Establish a governing board meeting the requirements of § 51c.304 by the end of the period of support under section 330(d)(1)(B) of the Act and this subpart.

§ 51c.404 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 330(d)(1)(B) of the Act and the applicable regulations of this part,

(1) Where the project meets the requirements of § 51c.403(a); and

(2) Taking into consideration the following:

(i) The degree to which the project would provide the services enumerated in § 51c.102(c)(1) and the feasibility of its providing all of such enumerated services by the end of the period of support under section 330(d)(1)(B) of the Act and this subpart;

(ii) Whether the project will have a governing board meeting the requirements of § 51c.304 by the end of the period of support under section 330(d)(1)(B) of the Act and this subpart;

(iii) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other Federally assisted health service or reimbursement programs or projects;

(iv) The need of the population to be served for the services to be provided;

(v) The potential of the project for the development of new and effective methods for health services delivery and management;

(vi) The soundness of the fiscal plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(vii) The administrative and management capacity of the applicant; and

(viii) The extent to which community resources will be utilized in the project.

(b) The Secretary may:

(1) Make no more than two grants for the same entity under section 330(d)(1)(B) of the Act;

(2) Not make any grant under section 330(d)(1)(B) to an entity which, for the same project, has been awarded more than one grant under section 330(c) of the Act;

(3) Not make a grant under section 330(d)(1)(B) to an entity which has been awarded a grant under section 330(d)(1)(A) of the Act.

Subpart E—Acquisition and Modernization of Existing Buildings

§ 51c.501 Applicability.

The regulations of this subpart, in addition to the regulations of the other applicable subparts of this part, are applicable to grants under section 330 of the Act for project costs which include the cost of acquisition and/or modernization of existing buildings (including the cost of amortizing the principal of, and paying the interest on, loans), except that, these regulations are not applicable to grants for project costs which include the costs of modernization of existing buildings if those costs can otherwise be supported under Subparts B, C, or D of this part.

[43 FR 5352, Feb. 7, 1978]

§ 51c.502 Definitions.

(a) "Equipment" means nonexpendable personal property as defined in 45 CFR 74.132.

(b) "Existing building" means a completed or substantially completed structure, and may include the realty on which it is or is to be located.

(c) "Modernization" means the alteration, repair, remodeling and/or renovation of a building (including the initial equipment thereof and improvements to the building's site) which, when completed, will render the building suitable for use by the project for which the grant is made.

[43 FR 5352, Feb. 7, 1978]

§ 51c.503 Application.

(a) *General requirements.* An application for a grant under this part for a project under Subparts B, C, or D which includes the acquisition and/or modernization of an existing building must include the following:

(1) A legal description of the site and a drawing showing the location of the building;

(2) A description of the architectural, structural, and other pertinent characteristics of the building sufficient to show that it is or that it will be, after alteration and renovation or after modernization, suitable for use by the project;

(3) A detailed estimate of the cost of the proposed acquisition and/or modernization;

(4) A description of, and copies of any relevant documents concerning, any existing or proposed financing arrangements for the acquisition and/or modernization;

(5) The proposed schedule for acquisition and/or modernization and occupancy;

(6) An assessment of the environmental impact of the proposed acquisition and/or modernization as called for by section 102(2)(c) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(c)) and such information as may be necessary to comply with the National Historic Preservation Act of 1966 (16 U.S.C. 470(f));

(7) Reasonable assurances that—

(i) The applicant has or will obtain a fee simple or such other estate or interest in the site, including necessary easements and rights-of-way, sufficient to assure for a period of not less than 20 years (in the case of interim facilities, for the period constituting the estimated useful life of such facilities) undisturbed use and possession for the purpose of the operation of the project;

(ii) The building will be used for the purposes for which the grant is made;

(iii) The building complies, or after alteration and renovation or after modernization will comply, with applicable State and local codes and with:

(A) "American National Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped" Number ANSI A117.1-1961 (R 1971), as modified by other standards prescribed by the Secretary or the Administrator of the General Services Administration. The applicant shall be responsible for conducting inspections to insure compliance with the specifications;

(B) The applicable standards set forth in Life Safety Code 1973, NFPA No. 101, which is hereby incorporated by reference and made a part hereof.

Copies of such document are available for examination at the Department's and Regional Offices' Information Centers listed in 45 CFR 5.31 and may also be obtained from the National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210 for $3.00 per copy.

(iv) In the case of a public applicant with an approved project which involves the displacement of persons or businesses on or after January 2, 1971, whose real property has or will be taken, the applicant will comply with the provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Pub. L. 91-646) and the applicable regulations issued thereunder (45 CFR Part 15);

(v) Sufficient funds will be available to meet any portion of the cost of acquiring and/or modernizing the building not borne by the grant under this part;

(vi) Sufficient funds will be available after acquisition and/or modernization of the building for effective use of the building for the purposes of the project;

(vii) The applicable requirements of the Flood Disaster Protection Act of 1973 have been met;

(8) Such other information as the Secretary may reasonably require.

(b) *Requirement for acquisition grants.* Except for a grant solely for amortization of principal and payment of interest on an existing loan, an application for a grant for a project which includes the acquisition of an existing building must include, in addition to the requirements of paragraph (a) of this section, evidence satisfactory to the Secretary that the applicant has explored other alternatives to the proposed acquisition (such as leasing facilities or acquiring other facilities in the project's catchment area) and that the proposed acquisition constitutes the soundest alternative from a financial and program standpoint.

(c) *Requirements for modernization grants.* In addition to the requirements of paragraph (a) of this section, an application for a grant for a project which includes modernization of an existing building must include the following:

(1) Plans and specifications for the proposed modernization which conform to the standards specified in § 51c.503(a)(7)(iii);

(2) Reasonable assurance that any laborer or mechanic employed by any contractor or subcontractor in the performance of work on the modernization project will be paid wages at rates not less than those prevailing on similar work in the locality as determined by the Secretary of Labor under the Davis-Bacon Act (40 U.S.C. 276a et seq.) and will receive compensation at a rate not less than one and one-half times his basic rate of pay for all hours worked in any workweek in excess of 8 hours in any calendar day; and

(3) Copies of any construction and materials contracts already entered into for the proposed modernization.

[41 FR 57000, Dec. 30, 1976, as amended at 43 FR 5352, Feb. 7, 1978]

§ 51c.504 Project elements.

(a) *General requirements.* A grantee which has received a grant under section 330 of the Act for a project which includes the acquisition and/or modernization of an existing building must:

(1) *Assurances.* Comply with the assurances provided pursuant to this subpart.

(2) *Approval of estimated cost.* Not enter into any contract for the acquisition and/or modernization funded under this subpart where the cost of such acquisition and/or modernization exceeds the estimates in the application, without the prior approval of the Secretary.

(3) *Non-default.* Make every effort to prevent any default on any loan secured by the building and, in the event of a default, promptly notify the Secretary of the default and make every effort on a timely basis to cure the default.

(b) *Requirements for acquisition grants.* In addition to the requirements of paragraph (a) of this section, a grantee which has received a grant under section 330 of the Act for a project which includes the acquisition of an existing building must:

(1) *Bona-fide sale.* Acquire or, in the case of a grant solely for amortization of principal and payment of interest on an existing loan, have acquired the existing building pursuant to a bona-fide sale involving an actual cost to the applicant and resulting in additional or improved facilities for the purposes of the project.

(2) *Standards of construction and equipment.* Except in the case of a grant solely for amortization of principal and payment of interest on an existing loan, obtain a determination by the Secretary that the facility conforms (or upon completion of any necessary alteration and renovation or modernization will conform) to the standards set forth in § 51c.503(a)(7)(iii) of this subpart before entering into a final or unconditional contract for the acquisition. Where the Secretary finds that exceptions to or modifications of any such standards would be consistent with the purposes of the Act and of the program, he may authorize such exceptions or modifications.

(3) *Financing.* Where the grantee will obtain a loan secured by the building in order to acquire the building, obtain such financing at the lowest current rate prevailing in the area for comparable loans on comparable facilities.

(c) *Requirements for modernization grants.* In addition to the requirements of paragraph (a) of this section, a grantee which has received a grant under section 330 of the Act for a project which includes the modernization of an existing building must:

(1) *Costs in excess of approved costs.* Finance all costs in excess of the estimated costs approved in the application and submit to the Secretary for prior approval any changes that substantially alter the scope of the function, utilities, or safety of the facility.

(2) *Competitive bids.* (i) Obtain the approval of the Secretary before the project is advertised or placed on the market for bidding; such approval must include a determination by the Secretary that the final plans and specifications conform to the standards set forth in § 51c.503(a)(7)(iii) of these regulations.

(ii) Except as otherwise provided by State or local law, contract for construction (including the purchase and installation of built-in equipment) on a lump sum fixed-price basis, and award contracts on the basis of competitive bidding obtained by public advertising with award of the contracts to the lowest responsive and responsible bidders. The provision for exceptions based on State and local law shall not be invoked to give local contractors or suppliers a percentage preference over non-local contractors bidding for the same contract. Such practices are precluded by this paragraph.

(3) *Construction contracts.* (i) Include the following conditions and provisions in all construction contracts for the modernization project:

(A) The provisions set forth in "DHHS Requirements for Federally Assisted Construction Contracts Regarding Labor Standards and Equal Employment Opportunities," Form DHHS 514 (rev. 7/76) (issued by the Office of Grants Administration Policy, U.S. Department of Health and Human Services) pertaining to the Davis-Bacon Act, the Contract Work Hours Standards Act, and the Copeland Act (Anti-Kickback) Regulations, except in the case of contracts in the amount of $2,000 or less; and pertaining to Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, relating to nondiscrimination in construction contract employment, except in the case of contracts in the amount of $10,000 or less;

(B) That the contractor shall furnish performance and payment bonds each of which shall be in the full amount of the contract price, and shall maintain, during the life of the contract, adequate fire, workmen's compensation, public liability, and property damage insurance: *Provided, however,* That in the case of a State or local unit of government which enters into a construction contract of less than $100,000, State or local provisions with respect to performance and payment bonds shall be deemed to meet the requirements of this paragraph; and

(C) That the Secretary shall have access at all reasonable times to work wherever it is in preparation or progress, and the contractor shall provide proper facilities for such access and inspection.

(ii) *Executive Order 11246.* Comply with the applicable requirements of Executive Order 11246, 30 FR 12319 (September 24, 1965) as amended, relating to nondiscrimination in construction contract employment, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

(4) *Modernization supervision.* Provide and maintain competent and adequate architectural or engineering supervision and inspection at the modernization site to insure that the completed work conforms with the plans and specifications.

(5) *Completion responsibility.* Complete the modernization in accordance with the grant application and the approved plans and specifications.

(6) *Progress reports.* Furnish progress reports and such other information concerning the modernization as the Secretary may require.

(d) The Secretary may at any time approve exceptions to the provisions of this section where he finds that such exceptions are not inconsistent with section 330 of the Act, other requirements of law, or the purposes of the program.

[41 FR 57000, Dec. 30, 1976, as amended at 43 FR 5352, Feb. 7, 1978]

§ 51c.505 Determination of cost.

The cost of acquisition and/or modernization of existing buildings for which funds may be granted under this part will be determined by the Secretary, utilizing such documentation submitted by the applicant as the Secretary may prescribe (including the reports of such real estate appraisers as the Secretary may approve) and other relevant factors, taking into consideration only that portion of the existing building necessary for the operation of the approved project.

[41 FR 5700, Dec. 30, 1976]

§ 51c.506 Use of grant funds.

Grant funds may be used to amortize the principal of or pay interest on a loan or mortgage on an existing building acquired under this part, including a building purchased by a grantee prior to the promulgation of this part, but only if the building is being used for the purposes of section 330 and complies with the applicable provisions of this subpart and only to the extent the Secretary finds such principal amounts and interest rates to be reasonable.

[41 FR 5700, Dec. 30, 1976]

§ 51c.507 Facility which has previously received Federal grant.

No grant for the acquisition of a facility which has previously received a Federal grant for construction, acquisition, or equipment shall serve either to reduce or restrict the liability of the applicant or any other transferor or transferee from any obligation of accountability imposed by the Federal Government by reason of such prior grant.

[41 FR 5700, Dec. 30, 1976]

PART 51d—GRANTS FOR SERVICE PROJECTS FOR GENETIC AND OTHER DISEASES

Subpart A—Grants for Hemophilia Treatment Centers

Sec.

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AUTHORITY: Secs. 215, 1131, Public Health Service Act, (42 U.S.C. 216, 300c-21); sec. 502(a), Social Security Act, as amended, 95 Stat. 819-20 (42 U.S.C. 702(a)).

SOURCE: 42 FR 56248, Oct. 21, 1977, unless otherwise noted.

Subpart A—Grants for Hemophilia Treatment Centers

§ 51d.101 Applicability.

The regulations of this subpart apply to grants to public and nonprofit private entities for projects for the establishment of comprehensive hemophilia diagnostic and treatment centers. For grants to entities in States that do not participate in the Maternal and Child Health Block Grant, as authorized by Title V of the Social Security Act (as amended by Public Law 97-35), the grants are awarded under section 1131 of the Public Health Service Act (42 U.S.C. 300c-21) as in effect before the enactment of Public Law 97-35. For entities in other States, the grants are awarded under section 502(a) of the Social Security Act (as amended by Public Law 97-35).

[47 FR 27825, June 25, 1982]

§ 51d.102 Definitions.

As used in this subpart:

(a) Except for references to the Social Security Act and except as set forth in § 51d.101, "Act" means the Public Health Service Act as in effect before the enactment of Public Law 97-35.

(b) "Applicant" means a public or nonprofit private entity which applies for a grant under this subpart.

(c) "Area of association" means the area outside a project's catchment area in which the project provides services in a program of association with providers of health care pursuant to § 51d.105(c) of this subpart.

(d) "Catchment area" means the area in which a project provides all of its services, except those provided pursuant to § 51d.105(c).

(e) "Center" means a project funded under this subpart.

(f) "Comprehensive care program" means a program detailing the appropriate treatment for an individual suffering from hemophilia which:

(1) Includes:

(i) An assessment of the type and severity of the individual's hemophilia condition;

(ii) Statements of the health care needed, including estimates of the individual's needs for prophylactic or replacement therapy, prophylactic dental care, physical therapy for prevention of secondary joint problems, and orthopedic treatment;

(iii) A statement of the activity (educational, recreational, and occupational) to be limited or avoided by the individual, or recommended for the individual;

(iv) Recommendations for periodic reevaluation (no less frequently than annually);

(v) Recommendations and/or referral for social and vocational counseling;

(vi) Recommendations and/or referral for genetic counseling; and

(vii) Information on 24-hour, 7-day-a-week emergency service; and

(2) Is developed by a multidisciplinary team which includes:

(i) Each of the following: a hematologist, a pediatrician or internist as appropriate, a nurse, and a social worker; and

(ii) If medically indicated, any one or more of the following: an orthopedist, a physical therapist, a psychiatrist, a psychologist, an oral surgeon or dentist, or an educational and/or vocational counselor.

(g) "Counseling" means consultation and advice provided by persons appropriately trained in their respective fields, and includes:

(1) Social counseling (counseling which is directed toward enhancing the social functioning of patients and their families through counseling about family relationships and interrelationships and helping to obtain tangible services, sources of referral for appropriate medical treatment, and sources of financial assistance for medical expenses);

(2) Vocational counseling (counseling concerning education, training, and employment suitable for hemophiliacs); and

(3) Genetic counseling.

(h) "Diagnosis" means the determination of the cause of significant bleeding tendencies.

(i) "Hemophilia" means a genetically transmitted bleeding disorder resulting from a deficiency of a plasma clotting factor.

(1) "Mild hemophilia" means a condition under which an individual:

(i) Generally leads a normal life, and

(ii) Has a sufficient amount of the clotting factor for blood to coagulate and bleeding to be controlled (in most cases, a circulating level of clotting factor above 10 percent of normal).

(2) "Moderate hemophilia" means a condition under which an individual:

(i) Rarely hemorrhages spontaneously but may experience significant hemorrhage after minor trauma, and

(ii) Has (in most cases) a circulating level of clotting factor that ranges from 1 to 10 percent of normal.

(3) "Severe hemophilia" means a condition under which an individual:

(i) Throughout his life is subject to spontaneous hemorrhage into soft tissue, bone joints, and muscles as well as bleeding after any type of trauma or minor surgery,

(ii) Has a circulating level of clotting factor that is usually less than 1 percent of normal.

(j) "Nonprofit" as applied to a private entity means that no part of the net earnings of such entity inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(k) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(l) "State" means any of the several States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

[42 FR 56248, Oct. 21, 1977, as amended at 47 FR 27825, June 25, 1982]

§ 51d.103 Eligibility.

Any public or nonprofit private entity is eligible to apply for a grant under this subpart.

§ 51d.104 Application for a grant.

An applicant for a grant under this subpart shall submit an application to the Secretary at such time and in such form and manner as the Secretary may prescribe, the application must contain:

(a) A full description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart.

(b) Evidence that the applicant consulted with appropriate community groups and hemophiliacs within the catchment area in developing its project.

(c) A budget and justification of the amount of grant funds requested.

(d) Evidence that the applicant is or within a reasonable time will become an approved provider of crippled children's services for hemophiliacs under Title V of the Social Security Act.

(e) A description of the precise boundaries of the catchment area which the applicant proposes to serve, and a description of the largest area outside that catchment area which the applicant cannot conveniently serve directly but can realistically serve through association with other health care providers who are treating individuals with hemophilia in a program of association meeting the requirements of § 51d.105(c) of this subpart.

(f) The estimated number of severe, moderate, and mild hemophiliacs residing in the applicant's proposed catchment area and the estimated number of those hemophiliacs in the proposed area of association.

(g) The estimated number of and a description of the programs for hemophiliacs within the applicant's catchment area and in the area of association, and the estimated number of hemophiliacs receiving care in each area under the programs.

(h) A statement of the method to be used to identify providers of health care who are treating individuals with hemophilia in the applicant's proposed area of association, and the method to be used to notify such providers of the services which the applicant will make available to them.

(i) The approximate number of hemophiliacs to be served by the applicant in its proposed area and area of association.

(j) An assurance satisfactory to the Secretary that the applicant will serve the maximum number of individuals that its available and potential resources will enable it effectively to serve.

(k) A description of the diagnostic and specialty treatment services to be offered and, in the case of an applicant already providing services to hemophiliacs, a description of all diagnostic, treatment, and other services for hemophiliacs being provided by the applicant.

(l) A description of the applicant's arrangements for access to an appropriate coagulation laboratory and an appropriate blood bank under § 51d.105(a) (1) and (2).

(m) The plans and curricula for training professional and paraprofessional personnel pursuant to § 51d.105(a)(3) of this subpart.

(n) Copies of position descriptions for key personnel to be utilized in carrying out the project, a statement indicating the need for the specific positions, and a description of the qualifications of principal staff members.

(o) A description of the counseling program to be provided pursuant to § 51d.105(b)(2) and of the arrangements to be made to provide social and vocational counseling.

(p) Such other pertinent information as the Secretary may require.

(q) Evidence that:

(1) The requirements of Part I of Office of Management and Budget Circular No. A-95 have been satisfied, and

(2) All applicable requirements for review and approval under title XV of the Act have been met.

(r) The signature of the individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the Act, the applicable regulations of this subpart, and any additional conditions of the grant award.

§ 51d.105 Project elements.

(a) *General requirements.* A project funded under this subpart must:

(1) Have a program to diagnose the type, degree, and nature of the bleeding tendency of individuals identified as probably suffering from hemophilia for the purpose of determining appropriate treatment. Such program shall include, at a minimum:

(i) Ready access to a coagulation laboratory that meets the standards set forth in 20 CFR Part 405, "Conditions of Coverage of Services of Independent Laboratories;" participates in the proficiency testing program of the Center for Disease Control; and which is capable of:

(A) Diagnosing any plasmatic factor deficiency,

(B) Identifying the existence of platelet functional disorders,

(C) Identifying the presence of inhibitors to one or more of the clotting factors, and

(D) Determining the existence of Factor VIII-related antigen, or obtaining access to this test by arrangement with another institution; and

(ii) Performing, at least annually, a test to detect inhibitors to one or more of the clotting factors on each hemophiliac served by the project who is receiving replacement therapy.

(2) Provide a program of comprehensive hemophilia treatment services, as specified in the grant award, of a specialized, multidisciplinary nature generally unavailable in its catchment area or area of association. This program may be carried out directly or on a referral basis, except that each project shall at a minimum—

(i) Have access to a blood bank which:

(A) Has expertise in preparing, evaluating, and storing therapeutic blood factors,

(B) Has available a comprehensive variety of blood products, including freeze-dried clotting factor concentrates, cryoprecipitates of plasma, and fresh or frozen whole plasma, and

(C) Relies, to the extent practicable, on voluntary donor sources for blood.

(ii) Provide to individuals served by the project prescriptions for blood products and directly provide blood products only when infused at and by the project; and

(iii) Provide training in home care to all hemophiliacs served by the project in need thereof and to the parents or guardians of such hemophiliacs who are minors.

(3) Provide a program of:

(i) Short-term training (not to exceed the equivalent of three months of fulltime training) in standards of hemophilia diagnosis and treatment to professional and paraprofessional personnel of the project and, as resources permit, to personnel concerned with the treatment of hemophiliacs, who work in the project's catchment area or area of association; and

(ii) Training of professional and paraprofessional project personnel in at least one selected area of hemophilia research.

(4) Develop, in consultation with the individual's primary physician, and provide to each hemophiliac served by the project (unless medically contraindicated) a written comprehensive care program.

(5) Serve as a clearinghouse for information on the availability of other programs of assistance and insurance for hemophiliacs, and assist hemophiliacs served by the project in making any necessary arrangements with those programs.

(6) Establish an outreach program to encourage all hemophiliacs and health care providers in the project's catchment area and area of association to participate in the program sponsored by the project.

(7) Provide for sufficient full- or part-time staff, qualified by training and experience, to carry out its activities.

(i) The staff shall include, at a minimum, a hematologist, internist, pediatrician, orthopedic surgeon, oral surgeon or dentist, physical therapist, registered nurse, and a social worker, except that if the hematologist is also an internist or a pediatrician an additional internist or pediatrician is not required to be on the staff.

(ii) The project must also insure the availability of a nutritionist, psychiatrist, psychologist, and an educational/vocational or rehabilitation counselor.

(8) Be, or within a reasonable time become, an approved provider of crippled children's services for hemophiliacs under the approved State plan under Title V of the Social Security Act for the State or States in which its catchment area and area of association lie.

(9) Make every reasonable effort to collect payment for services provided by the project in accordance with the applicable schedule of fees and payments for such services of the approved State plan referred to in paragraph (a)(8) of this section. Where a project provides services to residents of more than one State, the project shall provide services to residents of the State in which the project facility is located in accordance with the schedule of the State plan of that State, and shall provide services to residents of any other State served in accordance with an agreement with the State agency which administers the approved title V State plan of such other State concerning such fees and payments.

(10) Establish basic medical data, statistical data, cost accounting, management information and reporting systems which will enable the project to provide such statistics and other information as the Secretary may reasonably require relating to its costs of operation, patterns of utilization, and the availability, accessibility, acceptability, and effectiveness of its services, and to make these reports to the Secretary in a timely manner with such frequency as the Secretary may reasonably require.

(11) Provide for community participation, through establishment of an advisory council, if feasible, to advise with respect to the overall management of the project including services to be provided, the manner of their provision, and appointment of personnel. The membership of the advisory council must be representative of the population in the area served by the center, and include at least one hemophiliac receiving services from the center and at least two persons from separate family groups who are parents or guardians of hemophiliacs who are minors.

(12) Establish a formal referral system which will provide timely and necessary arrangements for eligibility, transfer of records, and a written referral for hemophiliacs who move to another treatment center's catchment area or area of association.

(b) *Requirements applicable to the project's catchment area only.* In addition to the requirements of paragraph (a) of this section, a project funded under this subpart must provide within its catchment area:

(1) Access to the services of the project for all individuals suffering from

hemophilia who reside in the catchment area and

(2) A program of counseling designed to assist hemophiliacs, who reside in the project's catchment area and are served by the center, to lead an independent life. Such counseling may be provided directly or by referral.

(c) *Requirements applicable to the area of association only.* In addition to the requirements of paragraph (a) of this section, a project funded under this subpart must provide a program of association with providers of health care who are treating individuals suffering from hemophilia residing outside the project's catchment area but within the area which the Secretary has determined (and has specified in the grant award) that the project cannot conveniently serve directly but can realistically serve with such a program. This program shall consist of at least the following:

(1) Implementation of a plan to identify and contact all providers of health services to hemophiliacs in the area of association and notify these providers of the project services available to them; and

(2) Institution of a program to attempt to enter into cooperative arrangements with these providers for the treatment of these hemophiliacs. Such arrangements must provide at a minimum for the following:

(i) Development by the project of individualized, written comprehensive care programs for hemophiliacs being treated by the providers in association with the project, with the participation and agreement of the providers in association.

(ii) Treatment of these hemophiliacs in accordance with the comprehensive care programs,

(iii) Provision for having these hemophiliacs visit the project for an annual re-evaluation of their medical and treatment status, and

(iv) Cooperation of the providers in association in arranging for social and vocational counseling for these hemophiliacs.

§ 51d.106 Accord with health planning.

A grant may be made under this part only if the applicable requirements of Title XV of the Act relating to review and approval by the appropriate health planning agencies have been met.

§ 51d.107 Grant evaluation and award.

(a) Within the limits of funds available, the Secretary may award grants to applicants which will, in his judgment, best promote the purposes of Title V of the Social Security Act, as amended by Pub. L. 97-35, and which submit approvable applications.

(1) In determining whether an application is approvable, the Secretary shall take into account:

(i) Whether it meets the requirements of this subpart;

(ii) The number of persons to be served by the project in relation to the grant funds requested; and

(iii) The extent to which rapid and effective use of grant funds will be made by the project, considering the following:

(A) The degree to which the project will be operated consistent with the hemophilia services part of the State plan for crippled children's services under Title V of the Social Security Act;

(B) The professional and technical competence of the project in hemophilia diagnosis, treatment, rehabilitation, and research;

(C) The potential integration of the project's services with other health service delivery programs;

(D) The soundness of the project's management; and

(E) The extent of community participation.

(2) The Secretary will give priority to projects that will operate in areas which the Secretary determines have the greatest number of severe and moderate hemophiliacs whose need for the services to be provided by such projects is unmet, as determined on the basis of the information supplied pursuant to § 51c.104.

(b) The amount of any award will be determined by the Secretary on the basis of his estimate of the sum necessary for the proper performance of the project. In determining the grantee's share of project costs, if any, costs borne by Federal funds, or costs used to match other Federal grants, may not be included except as may be otherwise provided by law.

(c) All grant awards shall be in writing, shall set forth the amount of funds granted, and the period for which support is recommended.

(d) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application periodically at such times and in such form as the Secretary may direct.

[42 FR 56248, Oct. 21, 1977, as amended at 47 FR 27825, June 25, 1982]

§ 51d.108 Payment.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award either in advance or by way of reimbursement for expenses incurred in the performance of the project, to the extent he determines these payments necessary to promote prompt initiation and advancement of the approved project.

§ 51d.109 Use of project funds.

(a) Any funds granted pursuant to this subpart, as well as other funds to be used in performance of the approved project, may be expended solely for carrying out the approved project in accordance with section 1131 of the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

(b) Project funds awarded under this subpart may be used, but need not be limited, to pay the costs of the following:

(1) Diagnosis and treatment services;

(2) Counseling services;

(3) Training professionals and paraprofessionals in hemophilia diagnosis, treatment, and research;

(4) Data collection and pooling of medical information;

(5) Transportation of patients, as necessary;

(6) Transportation and per diem for training professionals and paraprofessionals in association with the project;

(7) Public information;

(8) Delivering project services to hemophiliacs within the project's catchment area and area of association, within the following limitations: grant funds may be used to pay the portion of the reasonable cost of services provided in accordance with the schedule of fees and payments used pursuant to § 51d.105(a)(9) which, under such schedule, is uncompensated.

(c) Project funds awarded under this subpart shall not be used to pay the cost of:

(1) Inpatient hospital care;

(2) Provision of blood products except when the blood products are infused by and at the project as part of the course of treatment provided at the project.

(d) Grant funds shall not be used in lieu of other area funding sources to pay to support the program.

§ 51d.110 Civil rights.

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252 (42 U.S.C. 2000d et seq.)) and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of race, color, or national origin be excluded from participation, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary with the approval of the President (45 CFR Part 80). In addition, no person shall be denied employment in or by such program or activity on the grounds of age, sex, creed, or marital status.

(b) Attention is also called to the requirements of Section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

§ 51d.111 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff in connection with the provision of services under the project shall be treated as privileged communication, shall be held confidential, and shall not be divulged to any party including the provider in association without the individual's consent except as may be otherwise required by applicable law (including this subpart) or necessary to provide services to the individual. Such information may be disclosed in summary, statistical, or other form which does not identify particular individuals.

§ 51d.112 Publications and copyright.

Except as may be provided under the terms and conditions of the award, the Department of Health and Human Services copyright requirement set forth in 45 CFR 74.140, shall apply to any book or otherwise copyrightable material developed or resulting from the activity supported by a grant under this part.

§ 51d.113 Grantee accountability.

(a) *Accounting for grant award payments.* The grantee shall record all payments made by the Secretary in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project, the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirement of this subpart. *Provided, however,* that when the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed percentage rates applied to the total, or a selected element thereof, of the reimbursement direct costs incurred.

(b) *Grant closeout.* (1) Date of final accounting. A grantee shall render, with respect to each approved project, a full account as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (b) of this section.

(ii) Any credits for earned interest pursuant to paragraph (b) of this section.

(iii) Any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74.

(iv) Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

§ 51d.114 Performance and financial status reports.

A grantee shall submit a performance report meeting the requirements of 45 CFR 74.82(c), and a financial status report in accordance with 45 CFR 74.73.

§ 51d.115 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to all other grantee organizations under this subpart:

45 CFR PART 74

Subpart	
A	General.
B	Cash depositories.
C	Bonding and insurance.
D	Retention and custodial requirements for records.
F	Grant-related income.
G	Matching and cost sharing.
K	Grant payment requirements.
L	Budget revision procedures.
M	Grant closeout, suspension, and termination.
O	Property.

Subpart
Q Cost principles.

§ 51d.116 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of the award when, in his judgment, such conditions are necessary to assure or protect advancement of the approved project, the interest of public health, or the conservation of grant funds.

PART 51f—PROJECT GRANTS FOR GENETIC DISEASES TESTING AND COUNSELING PROGRAMS

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51f.102 Definitions.
51f.103 Who is eligible to apply for a genetic diseases testing and counseling grant?
51f.104 How is application made for a genetic diseases testing and counseling grant?
51f.105 What health planning requirements must be met?
51f.106 What requirements must be met by a genetic diseases testing and counseling project?
51f.107 What requirements must be met by a previously funded sickle cell project?
51f.108 What criteria will HHS use to decide which genetic diseases testing and counseling projects to fund?
51f.109 For what purposes may grant funds be used?
51f.110 What additional information should an applicant or grantee have about a genetic diseases testing and counseling grant?

AUTHORITY: Sec. 215, Public Health Service Act (42 U.S.C. 216); sec. 1101(a)(1), Public Health Service Act (42 U.S.C. 300b), as amended by Title II of Pub. L. 95-626, 92 Stat. 3570-3590; sec. 502(a) of the Social Security Act, as amended, 95 Stat. 819-20 (42 U.S.C. 702(a)).

SOURCE: 44 FR 23841, Apr. 23, 1979, unless otherwise noted.

§ 51f.101 To whom do these regulations apply?

The regulations of this part apply to grants for projects to plan, establish, and operate voluntary genetic diseases testing and counseling programs. For grants to entities in States that do not participate in the Maternal and Child Health Block Grant, as authorized by Title V of the Social Security Act (as amended by Pub. L. 97-35), the grants are awarded under section 1101(c) of the Public Health Service Act (42 U.S.C. 300b(a)(1)) as in effect before the enactment of Pub. L. 97-35. For entities in other States, the grants are awarded under section 502(a) of the Social Security Act (as amended by Pub. L. 97-35).

[47 FR 27825, June 25, 1982]

§ 51f.102 Definitions.

For the purposes of this part:

Except for references to the Social Security Act and except as set forth in § 51f.101, "Act" means the Public Health Service Act as in effect before the enactment of Pub. L. 97-35.

"Carrier" means a person who has a gene or chromosome which may cause a deleterious effect in his or her offspring.

"Genetic diseases" means inherited disorders caused by the transmission of certain aberrant genes from one generation to another.

"Nonprofit," as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefits, or may lawfully benefit, any private shareholder or individual.

"Secretary" means the Secretary of Health and Human Services or any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"Service area" means the area served by a project funded under Section 1101(a)(1) of the Act.

"State" means one of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

[44 FR 23841, Apr. 23, 1979, as amended at 47 FR 27825, June 25, 1982]

§ 51f.103 Who is eligible to apply for a genetic diseases testing and counseling grant?

Any public or nonprofit private entity is eligible to apply for a grant under this part.

§ 51f.104 How is application made for a genetic diseases testing and counseling grant?

An application for a grant under this part must be submitted to the Secretary at the time, and contain the information and assurances, required by the Secretary. The application must include a budget and narrative plan of the manner in which the project has met, or plans to meet, each of the requirements contained in § 51f.106(a), relating to genetic diseases testing and counseling projects, or § 51f.107, relating to previously funded sickle cell projects. The plan must describe the project in sufficient detail to identify clearly the nature, need, and specific objectives of, and methodology for carrying out, the project.

§ 51f.105 What health planning requirements must be met?

A grant may be made under this part only if the applicable requirements of Section 1513(e) of the Act relating to review and approval by the appropriate health systems agency have been met.

§ 51f.106 What requirements must be met by a genetic diseases testing and counseling project?

(a) *Project requirements.* All projects supported under this part, except previously funded sickle cell projects (described in § 51f.107), and, during the period in which they are engaged in planning activities, those projects described in paragraph (b) of this section, must:

(1) With respect to a broad range of genetic diseases, provide, or have the capability to provide, directly or through written agreements with providers, all of the following essential services:

(i) Individual testing, including those available and appropriate laboratory and clinical evaluation procedures which assure accurate diagnoses of carriers and persons who may have any of the genetic diseases proposed to be covered by the project; and all laboratory facilities used by the project must meet the standards set forth in 42 CFR Part 405, Conditions of Coverage of Services of Independent Laboratories, and must participate in the Center for Disease Control proficiency testing program;

(ii) Community-wide testing where appropriate, taking into consideration widely prevalent genetic diseases and certain high-risk population groups in which a genetic disease occurs with high incidence, and directed especially to persons who are entering their child-producing years;

(iii) Genetic counseling, to the extent of current knowledge in that field, for all persons concerned about having, or being carriers of, *any* genetic diseases;

(iv) A system for referral of persons to appropriate medical and supportive services, including the exchange of the patient's pertinent clinical records where necessary to provide services to the patient, consistent with the confidentiality requirements in § 51f.110(b), and followup procedures; and

(v) Facilitating services, such as transportation of patients to project facilities and interpreter services, where appropriate to ease access to project services.

(2) Provide, or have the capability to provide, directly or through written agreements with providers, the services described in paragraph (a)(1) of this section so that they are available and accessible promptly, including the provision of services in local facilities, as appropriate, to all of the residents of the service area, in a manner which will assure continuity of services. The service area may be no smaller than a State unless the Secretary waives this requirement for good cause shown.

(3) To the extent feasible, coordinate and integrate project activities with the activities of other federally funded, as well as State and local, health services and genetic disease-related programs serving the same service area.

(4) Provide its services through appropriately qualified individuals who meet applicable State and local licensure requirements and any other certification or legal requirements with respect to their respective professions. The project must monitor all activities supported under this part, whether provided directly or indirectly.

(5) Provide sufficient staff, qualified by training and experience, to ensure

that there is coordination of all service elements in the service area, and to ensure that project requirements are continually monitored and met.

(6) Have an ongoing quality assurance program administered by an identifiable unit which provides for periodic assessment of the use of services, and the appropriateness and quality of services provided or proposed to be provided to individuals served by the project.

(7) Assure that acceptance by any individual of services provided by the project is voluntary. An individual's acceptance of services may be deemed voluntary where he or she is legally incompetent and his or her legal representative consents to the provision of the services. The project must explain to patients and/or legal representatives the nature of the procedures proposed to be performed and significant risks and benefits that may be involved.

(8) Assure that all medical records and information about an individual patient will not be disclosed except in accordance with the requirements of § 51f.110(b). All written agreements between the project and other providers must contain assurances that the provider will maintain confidentiality of patient records and will not disclose information about patients except in accordance with the requirements of § 51f.110(b).

(9) Provide appropriate information and education for health care providers, teachers and students, and the general public, designed to achieve community understanding of the objectives of the program; inform the community of the availability of services; and promote participation in the project by persons to whom genetic diseases testing and counseling services may be beneficial.

(10) Provide for continuing community involvement in the development and operation of the project.

(11) Establish a fee schedule and a system for eligibility determination which is commensurate with these elements of the State Crippled Children's Services Program, established under Title V of the Social Security Act, in the project's State.

(12) Operate so that no person is denied service because of inability to pay.

(13) Make every reasonable effort, including the establishment of systems for eligibility determination, billing, and collection, to:

(i) secure payment from patients in accordance with the fee schedule described in paragraph (a)(11) of this section; and

(ii) collect reimbursement from third parties, to the extent that third parties (including Government agencies) are authorized or legally obligated to pay.

(14) Have a written agreement with third parties for reimbursement where a significant percentage of the cost of care and services provided by or through the project will be reimbursed by third parties. This requirement may be waived by the Secretary for good cause shown.

(b) *Requirements for planning.* Any project supported under this part whose application does not contain a plan satisfactory to the Secretary must:

(1) Develop a plan for the implementation of a comprehensive genetic diseases testing and counseling program, within a reasonable length of time, which (i) is based on an assessment of the need of the population proposed to be served for the services described in § 51f.106(a)(1), (ii) indicates in detail how the project will fulfill those needs and meet the requirements set forth in paragraph (a) of this section, and (iii) provides for the time-phased recruitment of personnel essential for operation of the project; and

(2) Submit the plan, developed in accordance with the requirements of paragraph (b)(1) of this section, to the Secretary for approval. The plan may be implemented only after the Secretary has determined that the proposed project will meet all of the requirements of paragraph (a) of this section.

§ 51f.107 What requirements must be met by a previously funded sickle cell project?

A sickle cell project which was previously funded under Section 301 of the Act and which receives funding under this part, in addition to meeting the requirements listed in § 51f.106(a) (2) through (14), must:

(a) Provide in its service area, directly or through written agreements with providers, all of the essential services listed in § 51f.106(a)(1) with respect to sickle cell anemia.

(b) Coordinate its services with an areawide network of genetic diseases testing and counseling services, if there is one in its service area, within the project year. The Secretary may waive this requirement for good cause shown.

§ 51f.108 What criteria will HHS use to decide which genetic diseases testing and counseling projects to fund?

(a) Within the limit of funds determined by the Secretary to be available for this purpose, the Secretary may award grants under this part to applicants which will, in his judgment, best promote the purposes of Title V of the Social Security Act, as amended by Pub. L. 97-35 and these regulations, taking into account:

(1) The extent to which the project would meet the requirements set forth in § 51f.106(a);

(2) The number of persons proposed to be served and the extent to which rapid and effective use of funds would be made;

(3) The comprehensiveness of the proposed project, with particular attention to the number of genetic diseases with respect to which the applicant intends to provide, either directly or indirectly, screening and testing services;

(4) The feasibility of the plan in the application for providing services;

(5) The degree to which the project will be operated in conjunction with programs supported under Title V of the Social Security Act, relating to Maternal and Child Health and Crippled Children's Services;

(6) The extent to which the project proposes to coordinate its activities with the activities of other health services and genetic disease-related programs, including federally assisted sickle cell projects, in the service area;

(7) Whether the project is or proposes to be a part of a network of services covering the entire service area;

(8) The capability of the applicant to provide sound financial management; and

(9) The applicant's plans for evaluation in such areas as management efficiency, the effectiveness of services, and the degree to which project goals will be met.

(b) *Priorities.* The Secretary will give priority to applicants for projects in areas which he determines have the greatest number of persons who may benefit from and are in need of genetic disease testing and counseling services. This determination will be based on the size of the general population of the proposed service area and the extent to which available resources are insufficient to meet the needs of that population for these services.

(c) *Previously funded sickle cell projects.* The Secretary will give special consideration to applications from entities which were funded under Section 301 of the Act in the preceding fiscal year for the conduct of sickle cell projects. The Secretary may support these projects under this part for one year so that they may develop and establish new, broad genetic diseases programs or be coordinated with an areawide network of genetic disease services, if one exists. If no areawide network of genetic disease services exists, or if coordination with an existing network could not, in the Secretary's judgment, reasonably be accomplished within one year, the Secretary may support these projects beyond one year. The Secretary may award grants to sickle cell projects which will, in his judgment, best promote the purposes of the Act and these regulations, taking into account:

(1) The extent of unmet need for sickle cell-related services in the service area;

(2) The effectiveness of the project's previous performance with respect to use of funds and provision of services;

(3) The effectiveness of the applicant's plan and the soundness of its management;

(4) Whether an areawide plan to cover a broad range of genetic diseases has been developed and will be implemented in a service area which includes the service area of the appli-

cant, during the project year for which the applicant requests funding;

(5) The effectiveness of the applicant's plan to become a service component in an areawide network of services within the project year, if an areawide network exists; and

(6) Whether the provision of sickle cell services would be terminated or rendered ineffective if funding were not approved.

[44 FR 23841, Apr. 23, 1979, as amended at 47 FR 27825, June 25, 1982]

§ 51f.109 For what purposes may grant funds be used?

(a) Grant funds awarded under this part may be used for, but need not be limited to, meeting the costs of the following:

(1) Genetic screening and testing;

(2) Confirmatory diagnostic procedures;

(3) Genetic counseling for persons found to have or to be carriers of genetic disease;

(4) Data collection;

(5) Facilitating services, such as transportation of patients to project facilities or interpreter services, as needed;

(6) Educational activities to promote public awareness and use of the project's services; and

(7) Planning activities, to the extent approved by the Secretary.

(b) Grant funds awarded under this part may not be used to support the costs of:

(1) Screening or testing procedures which are required by State law; or

(2) Inpatient or outpatient treatment services.

(c) Other funds available to the grantee for genetic testing and counseling services must be used, to the maximum extent possible, before using funds awarded under this part, and every reasonable effort must be made to maximize the receipt of funds from all other sources.

§ 51f.110 What additional information should an applicant or grantee have about a genetic diseases testing and counseling grant?

(a) *Applicability of HHS Department-wide regulations.* Attention is drawn to the following HHS Department-wide regulations which apply to grants under this part:

(1) 45 CFR Part 16—Department Grant Appeals Process.

(2) 45 CFR Part 74—Administration of Grants.

(3) 45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services's implementation of Title VI of the Civil Rights Act of 1964.

(4) 45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance.

(b) *Confidentiality.* All information as to personal facts and circumstances obtained by the project staff about recipients of services must be held confidential and must not be disclosed without the individual's informed consent, except as may be necessary to provide services to the patient or to provide for audits by the Secretary or the Comptroller General, with appropriate safeguards for confidentiality of patient records. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

(c) *Additional conditions.* The Secretary may with respect to any grant impose additional conditions prior to or at the time of any award when in his judgment these conditions are necesssary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

PART 51g—GRANTS FOR HEALTH EDUCATION-RISK REDUCTION

Sec.

51g.1 To which programs does this regulation apply?
51g.2 Definitions.
51g.3 Who is eligible to apply for a health education-risk reduction grant?
51g.4 What information must be included in the application for a grant?
51g.5 How will grant applications be evaluated and the grants awarded?
51g.6 For what period of time will grants be awarded?
51g.7 How may a grantee use grant funds?

Sec.
51g.8 Which other HHS regulations apply to these grants?
51g.9 Which other conditions apply to these grants?

AUTHORITY: Sec. 215, 56 Stat. 690 (42 U.S.C. 216); sec. 1703(a), 90 Stat. 697 (42 U.S.C. 300u-2(a)).

SOURCE: 45 FR 63846, Sept. 26, 1980, unless otherwise noted.

§ 51g.1 To which programs does this regulation apply?

This regulation applies to Health Education-Risk Reduction grants authorized under section 1703(a) of the Public Health Service Act (42 U.S.C. 300u-2(a)).

[45 FR 63486, Sept. 26, 1980, as amended at 46 FR 48593, Oct. 1, 1981]

§ 51g.2 Definitions.

As used in this regulation:

"Act" means the Public Health Service Act, as amended.

"Community-based activities" refers to Health Education-Risk Reduction methods and services, applied in settings other than schools, and directed toward a specific target group.

"Health Education-Risk Reduction" refers to program activities intended to encourage changes in personal choice behavior which may result in improving health and in lowering risks of developing or aggravating a preventable health condition (for example, trauma, unwanted pregnancy) or a chronic disease. Examples of personal choice behaviors include smoking, food selection, alcohol abuse, exercise, stress management, and safety practices.

"Intervention activity" means a specific health education program or combination of programs, provided to a defined target population, which is designed to reduce at least one specific health risk factor (for example, smoking cessation clinic, weekly employee group exercise program, and patient education class series on hypertension).

"Local health agency" refers to a health agency which is a part of, and under the direction of, a city, county, township, town, borough, parish, village, or other general purpose political subdivision of a State.

"Minority" refers to Asians, Blacks, Hispanics, Native Americans (including American Indians, Eskimos, and Aleuts), and Pacific Americans.

"Organized approach to risk reduction" is a community undertaking characterized as follows:

(a) The community is a definable geographical area (for example, a county or counties, town, city, health district, Indian reservation, federation of natives).

(b) A lead agency or organization within the community is identified and liaisons are established among multiple agencies to:

(1) Determine the prevalence of risk factors for the population in the community.

(2) Establish objectives to reduce the prevalence of risk factors in the community.

(3) Describe each current activity or commitment to reduce the prevelance of risks in the community.

(4) Perform a periodic reassessment of the status of priority risk factors within the community.

"School-based activities" refers to methods and services applied in a school setting or directed toward a target group defined by enrollment in an individual school or school system but which may be offered outside regular school hours.

"Secretary" means the Secretary of Health and Human Services (HHS) and any other officer or employee of the Department to whom the authority involved has been delegated.

"State" means one of the 50 States, the District of Columbia, Guam, Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

"State-level program" refers to the State health agencies overall coordination, operational management, and provision of technical assistance required to achieve the Health Education-Risk Reduction program's *Basic Program Elements* as specified in § 51g.4(b).

"Target population" means a defined group of persons toward which Health Education-Risk Reduction services and programs will be directed as part of an intervention activity.

§ 51g.3 Who is eligible to apply for a health education-risk reduction grant?

(a) Any State health agency is eligible to apply for a grant for a State-level program and for intervention activities.

(b) A local health agency, as authorized by the political subdivision of the State, may submit an application for funding for an intervention activity directly to the Secretary when:

(1) The State health agency does not submit an application to the Secretary for funding of a State-level program, and

(2) The local health agency's intervention activity application is submitted through, and receives the approval of, the State health agency.

(c) Other public health and education agencies, private and voluntary organizations, and native American tribal councils or federation of natives are encouraged to apply to their respective State-level grantee for funding through the State for intervention activities as defined in § 51g.2.

§ 51g.4 What information must be included in the application for a grant?

(a) A grant application must include a project plan which describes clearly and concisely information on the points below:

(1) Budget information:

(i) Items detailing the State level program.

(ii) Itemized budgets for each individual intervention proposal.

(iii) Allocation of shared personnel costs.

(iv) Narrative description and justification of all budget items.

(2) Background and need:

(i) Political subdivision included in the project.

(ii) Structure of health department.

(iii) Current population (age groups).

(iv) Ethnic and geographic characteristics.

(v) Morbidity and mortality data or a plan for establishing a system to collect morbidity data if not already established.

(vi) Facilities and resources which are or will be available to implement the program.

(vii) Interrelationship with other Federally assisted programs.

(viii) Additional State and/or community resources which can be mobilized.

(3) Project objectives:

(i) The objectives must be specific, measurable, and realistic.

(ii) The objectives must relate to outcomes which can be described on a community-level or specific target group level, using the common data items provided.

(iii) Both short-term (1-year budget period) and long-term (project period) objectives must be stated.

(4) Intervention proposals.

(5) A list of intervention proposals (received from other agencies) which were not included in the application and the criteria and rationale for not including them.

(b) In addition to the requirements in § 51g.4(a), the State-level proposals must include the following *Basic Program Elements* which establish the State-level program as the principal organization to coordinate grant program activities:

(1) Updating and maintenance of an inventory of existing Health Education-Risk Reduction activities ongoing in the State.

(2) Maintenance of working liaisons directed toward developing cooperative strategies with voluntary health agencies, professional organizations, and education groups (examples, State and local boards of education, other State and local agencies, school system, Parent-Teacher Associations, Cooperative Extension Services) which have potential for positively affecting risk reduction activities.

(3) If the State-level grant application contains smoking and alcohol intervention proposals, a detailed plan must be submitted which describes the formal relationship and linkage with the State educational and State alcohol agencies, and a plan to work with these agencies to monitor and provide technical assistance to funded intervention activities.

(4) Development and/or improvement of surveillance systems to identify and record the morbidity and mortality of chronic diseases and their related risk factors. This process should

be coordinated with existing data collection systems, where appropriate and available.

(5) Provision of technical and management consultation to communities to establish, maintain, and improve "an organized approach to risk reduction" as defined in § 51g.2. Specifically, the State-level program must be capable of:

(i) Assisting community organizations to recognize mutual interests and complementary efforts.

(ii) Identifying resources outside of communities which may assist local efforts.

(iii) Providing assistance to determine the prevalence of risks within the community or specific target populations, develop local objectives and work plans, and select health education/promotion methods.

(6) Stimulating intervention activity proposals to compete for Federal funding which address specific target groups and are supported by specific, measurable objectives.

(7) Documenting efforts to stimulate intervention activity proposals which address highly susceptible populations and minority target populations.

(8) Monitoring intervention activities which receive Federal grant support to assure that activities are adquately carried out.

(c) Intervention activity proposals may be submitted to the State health agency by a wide variety of organizations and agencies. (See § 51g.3, "Who Is Eligible To Apply * * *?")

(1) Intervention activity proposals must include the following:

(i) A description of the need and rationale for carrying out the proposed activities in the selected target population.

(ii) A review of the current or previous Health Education-Risk Reduction efforts within the selected target population.

(iii) A description of existing Health Education-Risk Reduction services, resources, or facilities within the community which may complement the activities proposed for the selected target population.

(iv) A plan to document the prevalence of risk factors using common data items.

(v) A work plan describing the delivery of proposed health education programs and risk reduction services to the selected target population which will result in reducing the identified prevalence of risk factors.

(vi) A plan to periodically monitor and evaluate the implementation and effectiveness of applied methodology.

[45 FR 63486, Sept. 26, 1980, as amended at 46 FR 48593, Oct. 1, 1981]

§ 51g.5 How will grant applications be evaluated and the grants awarded?

The Secretary may award grants for projects which will best promote the purposes of section 1703(a) of the Act. In making this determination:

(a) Each State-level grant application will be reviewed and judged according to the following criteria:

(1) Is each of the Basic Program Elements likely to be achieved satisfactorily?

(2) Is there a logical method of operation specified for each proposed activity?

(3) Has the applicant developed adequate plans for involving public, private, and voluntary agencies in health education activities in the project area and have plans been made to effectively use existing community resources?

(4) Are the project objectives specific, measurable, realistic, and related to the national program goals?

(5) Have effective evaluation measures been specified?

(6) With respect to previous grants, have the prior year's accomplishments been satisfactory and on schedule?

(7) Have appropriate data been collected and used for planning purposes?

(8) Does the application provide a clear understanding of whom the program will serve and who is responsible for the various activities?

(9) Are budget requests and proposed uses of grant funds reasonable considering the anticipated results?

(10) Have project personnel been recruited and are they well qualified by training and/or experience for the support sought?

(11) Do the proposed activities follow a logical pattern to achieve the stated objectives?

(12) Are the program objectives based upon well-defined problems derived from baseline data and other assessments?

(13) Is the inventory of resources related to the intervention activities in such a way that a clear intent is evident to utilize the resources as much as possible?

(14) Will the evaluation plan adequately measure program accomplishments and identify successes and failures of specific health education methods to redirect future efforts?

(15) Does a viable complementary relationship exist between the State-level program and proposed intervention activities?

(b) Each intervention proposal will be judged on its own merits, in competition with all the other intervention proposals submitted to the Secretary. The application will have the best opportunity of success if the need for the activity has been carefully assessed and if the activity can be successfully completed in a reasonable period of time. Proposals will be judged according to the following criteria:

(1) Technical quality.

(2) The extent to which the proposal complements or enhances the efforts of a community which is undertaking "an organized approach to risk reduction," and the extent to which the proposal addresses highly susceptible populations and minority target populations.

(3) Potential for replication at other sites at reasonable costs.

(4) Conformity and linkage with State-level programs and other appropriate agencies.

(5) Contributions toward new knowledge, techniques, and services.

(6) National or regional application of results.

(7) Applicant participation and plans for other than Federal funding.

(8) Availability and adequacy of resources.

(9) Adequacy of the evaluation plan to measure program outcomes, impacts, and processes.

[45 FR 63846, Sept. 26, 1980, as amended at 46 FR 48593, Oct. 1, 1981]

§51g.6 For what period of time will grants be awarded?

(a) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 5 years.

(b) Generally, the grant will initially be funded for 1 year and subsequent continuation awards will also be for 1 year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(d) The Secretary may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the Secretary's written approval is obtained. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 51g.7 How may a grantee use grant funds?

Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the applicable regulations in this part, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

§ 51g.8 Which other HHS regulations apply to these grants?

Several other HHS regulations apply to grants under this part. These include, but are not limited to:

42 CFR Part 50—Subpart D, Public Health Service Grant Appeals Procedure

42 CFR Part 122—Subpart E, Health Systems Agency Reviews of Certain Proposed Uses of Federal Health Funds

45 CFR Part 16—Department Grant Appeals Process

45 CFR Part 74—Administration of Grants

45 CFR Part 75—Informal Grant Appeals Procedures

45 CFR Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and Procedure for Hearings Under Part 80

45 CFR Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance

45 CFR Part 86—Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving or Benefiting from Federal Financial Assistance

45 CFR Part 90—Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance

§ 51g.9 Which other conditions apply to these grants?

The Secretary may, with respect to any grant award, impose additional conditions at the time of the grant award when the Secretary determines that they are necessary to advance the approved program, the interest of the public health, or the conservation of grant funds.

PART 52—GRANTS FOR RESEARCH PROJECTS

Sec.

52.1 To which programs do these regulations apply?
52.2 Definitions.
52.3 Who is eligible to apply for a grant?
52.4 How to apply for a grant.
52.5 Evaluation and disposition of applications.
52.6 Grant awards.
52.7 Use of funds; changes.
52.8 Other HHS regulations that apply.
52.9 Other conditions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 63 Stat. 835 (42 U.S.C. 216); sec. 301, 58 Stat. 691, as amended, 60 Stat. 423, 62 Stat. 467, 601, 1017, 70 Stat. 490, 74 Stat. 1053, 85 Stat. 785, 86 Stat. 687, 88 Stat. 346, 360 (42 U.S.C. 241); sec. 303, 70 Stat 929, as amended, 84 Stat. 1241, 88 Stat. 132, 346 (42 U.S.C. 242a); sec. 356, 82 Stat. 1174 (42 U.S.C. 263d); sec. 394, 79 Stat. 1062, as amended, 84 Stat. 63, 64, 66, 67, 87 Stat. 92, 88 Stat. 372 (42 U.S.C. 280b-5); sec. 1004, 89 Stat. 306, 352, as amended, 91 Stat. 389 (42 U.S.C. 300a-2); sec. 1006, 89 Stat. 308 (42 U.S.C. 300a-4); sec. 501, 90 Stat. 1038 (42 U.S.C. 4585); sec. 1205, 87 Stat. 597 (42 U.S.C. 300d-4); sec. 410, 68 Stat. 84, as amended, 90 Stat. 247, 90 Stat. 1040 (21 U.S.C. 1177); sec. 309(b), 92 Stat. 3447 (42 U.S.C. 242n).

SOURCE: 45 FR 12240, Feb. 25, 1980, unless otherwise noted.

§ 52.1 To which programs do these regulations apply?

(a) The regulations of this part apply to grants for the support of health-related research projects in programs relating to:

(1) The cause, diagnosis, treatment, control, or prevention of the physical or mental diseases, injuries, or impairments to human life, as authorized by sections 301, 303, and related provisions of the Act (42 U.S.C. 241, 242a);

(2) Electronic product radiation control programs designed to protect the public, and safety from electronic product radiation, as authorized by section 356 of the Act (42 U.S.C. 263d);

(3) Medical library science and related activities, and for the development or dissemination of new knowledge, techniques, systems, and equipment for processing, storing, retrieving, and distributing information pertaining to health sciences, as authorized by section 394 of the Act (42 U.S.C. 280b-5);

(4) Emergency medical techniques, methods, devices, and delivery, as authorized by section 1205 of the Act (42 U.S.C. 300d-4);

(5) The behavioral and biomedical etiology, treatment, mental and physical health consequences, and social and economic consequences, of alcohol abuse and alcoholism, as authorized by section 501 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4585);

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(6) The improvement of drug maintenance techniques or programs, as authorized by section 410 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1177);

(7) Research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population, as authorized under section 1004 of the Act; and

(8) Health care technology assessments, including studies of the safety, efficacy, effectiveness, and cost effectiveness of particular technologies, their social, ethical, and economic impacts, as well as studies of methods of dissemination of information about technologies, and factors affecting the use of technologies as authorized by section 309(b) of the Act (42 U.S.C. 242n).

(b) These regulations do not apply to general research support grants, grants for the construction of research facilities (see Part 57 of this chapter), for the construction of hospital or other medical facilities (see Part 53 of this chapter), or the award of fellowships (see Part 61 of this chapter), traineeships (see Part 63 of this chapter), training grants (see Part 64 of this chapter), or to the support of research training under the National Research Service Awards program (see Part 66 of this chapter).

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980, as amended at 46 FR 4919, Jan. 19, 1981]

§ 52.2 Definitions.

As used in this part:

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

(b) "Principal investigator" means a single individual designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project.

(c) "Act" means the Public Health Service Act (42 U.S.C. 201 et seq.).

(d) "Department" means the Department of Health and Human Services.

(e) "Grantee" means the institution, organization, individual or other person designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part.

(f) "Research project grant" means the award by the Secretary of funds to a grantee to assist in meeting the costs of conducting for the benefit of the public health an identified project which is intended and designed to establish, discover, develop, elucidate or confirm information or the underlying mechanisms relating to a program set forth in § 52.1.

(g) "Project" means the particular activity within the scope of one or more of the programs set forth in § 52.1 which is supported by a grant award under this part.

§ 52.3 Who is eligible to apply for a grant?

(a) *Persons eligible.* Any individual, corporation, public or private institution or agency, or other legal entity shall be eligible for a grant award except:

(1) An individual or entity which is otherwise ineligible for an award under applicable law or regulation, and

(2) Federal agencies or institutions unless specifically authorized by law to receive the grant.

(3) Any individual, corporation, institution, agency or other entity that, having previously received a grant award, has failed willfully and materially in the judgment of the Secretary to comply with accounting or other requirements applicable to that prior award. Ineligibility for a grant award under this paragraph continues until terminated in the public interest by the Secretary.

(b) *Permissible activities within projects.* Any project found by the Secretary to be a research project within the meaning of § 52.1 shall be eligible for a grant award. Eligible projects may consist of laboratory, clinical, population, field, statistical, basic, applied or other types of investigations, studies or experiments, or combinations thereof, and may either be limited to one, or a particular aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation and involving multiple disciplines, facilities and resources.

[45 FR 12240, Feb. 25, 1980, as amended at 46 FR 58675, Dec. 3, 1981]

§ 52.4 How to apply for a grant.

A grant application must include the following information:

(a) Nature requested project period, purpose and plan of the project;

(b) Name and qualifications of the principal investigator and any other key personnel;

(c) Qualifications of the principal staff members to be responsible for the project;

(d) The total facilities and resources that will be available;

(e) Justification of the amount of grant funds requested; and

(f) Other pertinent information the Secretary may require to evaluate the proposed project.

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52.5 Evaluation and disposition of applications.

(a) *Evaluation.* All applications filed in accordance with § 52.4 shall be evaluated by the Secretary through such officers and employees and such experts or consultants engaged for this purpose as the Secretary determines are specially qualified in the areas of research involved in the project, including review by an appropriate National Advisory Council or other body as may be required by law. The Secretary's evaluation shall take into account among other pertinent factors the scientific merit and significance of the project, the competency of the proposed staff in relation to the type of research involved, the feasibility of the project, the likelihood of its producing meaningful results, the proposed project period, and the adequacy of the applicant's resources available for the project and the amount of grant funds necessary for completion, and in the case of applications for support of research in emergency medical services, special consideration shall be given to applications for grants for research relating to the delivery of emergency medical services in rural areas.

(b) *Disposition.* On the basis of the Secretary's evaluation of an application in accordance with paragraph (a) of this section and subject to approvals, recommendations or consultations by the appropriate National Advisory Council or other body as may be required by law, the Secretary will (1) approve, (2) defer because of either lack of funds or a need for further evaluation, or (3) disapprove support of the proposed project in whole or in part. With respect to approved projects, the Secretary will determine the project period (subject to extension as provided in § 52.7(c)) during which the project may be supported. Any deferral and disapproval of an application will not preclude its reconsideration or a reapplication.

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52.6 Grant awards.

(a) *General.* Within the limits of funds available for such purpose, the Secretary shall award a grant to those applicants whose approved projects will in the Secretary's judgment best promote the purposes of § 52.1. The date specified by the Secretary as the beginning of the project period shall be no later than 9 months following the date of any initial or new award statement unless the Secretary finds that because of the nature of a project or the grantee's particular circumstances earlier assurance of grant support is required to initiate the project. Any funds granted under this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

(b) *Notice of grant award.* (1) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 1-5 years.

(2) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(3) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(c) *Multiple, concurrent, initial awards.* Whenever a reseach project involves a number of different but related problems, activities or disciplines which require evaluation by different groups, or whenever support for a project could be more effectively administered by separate handling of separate aspects of the project, the Secretary may evaluate and approve two or more concurrent applications each dealing with one or more specified aspects of the project, and the Secretary may make two or more concurrent grant awards with respect to such a project.

(d) *Unobligated balances.* The Secretary may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the Secretary's written approval is obtained.

(e) *Award for continuation of project under new grantee.* The Secretary, upon application in accordance with the provisions of § 52.4 and without further action by a Council or other body, may make a grant to any institution or other person eligible under § 52.3 for continuation of a currently supported project for which a grant was previously made to another institution or person, provided the Secretary finds that the change in the conduct of the project is consonant with the previous evaluation and approval of the project under § 52.5.

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52.7 Use of funds; changes.

(a) *Delegation of fiscal responsibility.* The grantee may not in whole or in part delegate or transfer to another person responsibility for the use or expenditure of grant funds.

(b) *Changes in project.* The permissible changes by the principal investigator in the approved project shall be limited to changes in methodology, approach or other aspects of the project to expedite achievement of the project's research objectives, including changes that grow out of the approved project and serve the best scientific strategy. If the grantee and the principal investigator are uncertain whether a change complies with this provision, the question must be referred to the Secretary for a final determination.

(c) *Changes in project period.* The project period determined pursuant to § 52.5(b) may be extended by the Secretary, with or without additional grant support, for such an additional period as the Secretary determines may be required to complete, or fulfill the purposes of, the approved project.

§ 52.8 Other HHS regulations that apply.

Several other HHS regulations apply to grants under this part. These include but are not limited to:

42 CFR Part 50, Subpart D—PHS grant appeals procedure

45 CFR Parts 6 and 8—Inventions and patents

45 CFR Part 16—Department grants appeals process

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants (including grants to individuals)

45 CFR Part 75—Informal grant appeals procedures (indirect costs rates and other cost allocations)

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in federally assisted education programs and activities

45 FR 6724—Guidelines for Research involving Recombinant DNA Molecules, published by the National Institutes of Health

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52.9 Other conditions.

The Secretary may with respect to any grant award or class of awards impose additional conditions prior to or at the time of any award when in the Secretary's judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

PART 52a—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE GRANTS FOR NATIONAL RESEARCH AND DEMONSTRATION CENTERS

Sec.
52a.1 Applicability.
52a.2 Definitions.
52a.3 Eligibility.
52a.4 Application.
52a.5 Program requirements.
52a.6 Grant awards.
52a.7 Expenditure of grant funds.
52a.8 Other HHS regulations that apply.
52a.9 Additional conditions.

Authority: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 415(b), 86 Stat. 683 (42 U.S.C. 287d(b)).

Source: 45 FR 12242, Feb. 25, 1980, unless otherwise noted.

§ 52a.1 Applicability.

The regulations in this part apply to grants (other than for construction) to plan, establish, strengthen, and support the basic operation of National research and demonstration centers for basic or clinical research into, training in and demonstration of the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, and blood diseases, as authorized by section 415(b) of the Public Health Service Act (42 U.S.C. 287d(b)).

§ 52a.2 Definitions.

(a) "Act" means the Public Health Service Act, as amended.

(b) "Director, NHLBI," means the Director of the National Heart, Lung, and Blood Institute and any other officer or employee of said Institute to whom the authority involved has been delegated.

(c) "Nonprofit" as applied to any agency or institution means an agency or institution which is a corporation or an association no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

(d) "Council" means the National Heart, Lung, and Blood Advisory Council established by section 417(a) of the Act (42 U.S.C. 287f(a)).

(e) "National Program" means the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources program referred to in section 413 of the Act (42 U.S.C. 287b).[1]

§ 52a.3 Eligibility.

To be eligible for a grant under this part, an applicant must be:

(a) A public or nonprofit private hospital or school of medicine, or other public or nonprofit private agency or institution; and

(b) Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

§ 52a.4 Application.

(a) Application for a grant under this subpart shall be made on an authorized form.[2] Applicants shall submit completed forms on or before the dates the Director, NHLBI, may prescribe.

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[1] Single copies of the National Program are available upon request from the Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20205.

[2] Applications and instructions are available from the Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20205.

(b) Each private institution which does not already have on file with the National Institutes of Health evidence of nonprofit status, must submit with its application acceptable proof of such status.

(c) In addition to any other pertinent information that the Director, NHLBI, may require, each application shall set forth in detail:

(1) The personnel, facilities, and other resources currently available to the applicant with which to initiate and maintain the proposed center program;

(2) Any basic or clinical research, training, or demonstration activities in which the applicant is currently engaged relating to the management of blood resources or advanced diagnostic prevention, or treatment methods for heart, blood vessel, lung, or blood diseases; the sources of funding for such activities; and the relevance of these activities to the National Program;

(3) The major area or areas (i.e., heart disease, blood vessel disease, lung disease, blood disease, or management of blood resources) on which the applicant would concentrate if awarded a grant under this part;

(4) The names and qualifications of the center director and key staff members who would be responsible for conducting proposed activities of the center;

(5) The proposed center program, including proposed research and demonstration projects and information and education activities, and the relevance of each to the National Program;

(6) The opportunities that would be available for training of professional personnel, including allied health professions personnel;

(7) The availability of community resources necessary to carry out the proposed activities;

(8) The organizational structure of the applicant;

(9) The proposed support project period (not to exceed five years); a detailed budget for the first budget period including a list of other anticipated sources of support and anticipated total needs for each of the succeeding budget periods of the requested project period; and a justification for the amount of grant funds (not exceeding $5,000,000 in the aggregate for costs other than indirect costs in any year, plus any added amounts attributable to increases in such year in appropriate costs as reflected in the Consumer Price Index published by the Bureau of Labor Statistics);

(10) Proposed methods for monitoring and evaluating individual activities and the overall program; and

(11) Proposed methods for coordination of center activities with the National Heart, Lung, and Blood Institute and the National Program.

[45 FR 12242, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52a.5 Program requirements.

An approvable application must include information indicating that:

(a) The proposed program will include all of the following components: basic and clinical research relating to the major areas on which the applicant would concentrate; plans for demonstrating the applicability of clinical research findings in such areas; information and education activities pertaining to such areas; and opportunities for training, including training of allied health professions personnel;

(b) The center will be an identifiable organizational unit of the applicant headed by a center director responsible for the center program; and

(c) The applicant will have staff, facilities, and other resources available with which to initiate the proposed program.

§ 52a.6 Grant awards.

(a) Within the limits of funds available, after consultation with the Council, the Director, NHLBI, may award grants to applicants with proposed programs which in the Director's judgment best promote the purposes of section 415(b) of the Act, taking into consideration among other pertinent factors:

(1) The scientific and technical merit of the overall proposed program and its individual components;

(2) The significance of said program in relation to the goals of the National Program;

(3) The qualifications and experience of the center director and other key personnel;

(4) The extent to which the center activities would be coordinated with the National Heart, Lung, and Blood Institute and the National Program;

(5) The extent to which the various components of the proposed program would be coordinated into one multidisciplinary effort within the center;

(6) The administrative and managerial capability of the applicant;

(7) The reasonableness of the proposed budget in relation to the proposed program;

(8) The adequacy of the methods for monitoring and evaluating the overall program and its components; and

(9) The degree to which the application adequately provides for the requirements set forth in § 52a.5.

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 1-5 years.

(c) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

(e) An initial project period may be extended by the Director, NHLBI, for additional periods not in excess of five years each, after review of the operations of the grantee by an appropriate scientific review group established by the Director, NHLBI, and consultation with the Council, except that if an additional period of support involves only the expenditure of funds previously awarded, consultation with the Council is not required.

[45 FR 12242, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52a.7 Expenditure of grant funds.

(a) Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

(b) The Director, NHLBI, may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the NHLBI Director's written approval is obtained. The amount of any subsequent award will take into consideration unobligated grant funds remaining in the grant account.

§ 52a.8 Other HHS regulations that apply.

Several other regulations apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50—PHS grant appeals process

45 CFR Part 16—Department grant appeal process

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates, and other cost allocations)

45 CFR Part 80—Nondiscrimination under program receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Regulation for the Administration and Enforcement of Section 704 and 855 of the PHS Act

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from federal financial assistance

45 FR 6724—Guidelines for Research Involving Recombinant DNA Molecules, published by the National Institutes of Health

[45 FR 12242, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52a.9 Additional conditions.

The Director, NHLBI, may with respect to any grant award impose additional conditions prior to or at the time of any award when in the Director's judgment those conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

PART 52b—NATIONAL CANCER INSTITUTE CONSTRUCTION GRANTS

Sec.
52b.1 Applicability.
52b.2 Definitions.
52b.3 Eligibility.
52b.4 Application.
52b.5 Evaluation.
52b.6 Other HHS regulations that apply.
52b.7 Rate of Federal financial participation.
52b.8 Terms and conditions.
52b.9 Acquisition of facilities.
52b.10 Additional conditions.
52b.11 Minimum standards of construction and equipment.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 406(b), 92 Stat. 3428 (42 U.S.C. 286a); sec. 404(b)(9), 92 Stat. 3427 (42 U.S.C. 285).

SOURCE: 45 FR 12243, Feb. 25, 1980, unless otherwise noted.

§ 52b.1 Applicability.

The provisions of this part apply to award of grants under section 406(b) of the Public Health Service Act for the construction of centers for clinical research, training and demonstration of advanced diagnostic and treatment methods relating to cancer, and to the award of grants under section 404(b)(9) for construction of basic research laboratory facilities.

§ 52b.2 Definitions.

(a) "Act" means the Public Health Service Act, as amended.

(b) "Director" means the Director of the National Cancer Institute and any officer or employee of the National Cancer Institute to whom the authority involved may be delegated.

(c) "Construction grant" means a grant of funds for construction pursuant to sections 406(b) and 404(b)(9) of the Act, and in accordance with these regulations.

(d) "Construction" includes the construction of new buildings; acquisition of land or existing buildings provided such acquisition occurs after the filing of the application; the expansion, remodeling, and alteration of existing buildings provided the cost of such expansion, remodeling, and alteration is not less than $75,000; and the initial equipment of any such buildings; but excludes the cost of off-site improvements.

§ 52b.3 Eligibility.

In order to be eligible for a construction grant under section 406(b) or section 404(b)(9) of the Act, the applicant must be:

(a) A public or private nonprofit agency or institution; and

(b) Located in a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Canal Zone, American Samoa, the Trust Territory of the Pacific Islands, or Guam.

§ 52b.4 Application.

(a) *Submittal.* Applications for construction grants under section 406(b) or section 404(b)(9) of the Act, including both detailed narrative descriptions and detailed estimates of the cost of the respective projects, shall be made on an authorized form.

(b) *Environmental impact.* Each applicant shall furnish its analysis of the environmental impact of the proposed construction taking into account the consideration set forth in the National Environmental Policy Act, Pub. L. 91-190 ((42 U.S.C. 4321 et seq.), 83 Stat. 852).

(c) *Flood hazards.* Each applicant shall furnish its assessment of the project site in light of the considerations set forth in Executive Order 11296, 31 FR 10663 (August 10, 1966) concerning the evaluation of flood hazards in locating Federally supported facilities.

(d) *Review by State and local comprehensive health planning agency.* In the case of a project for the construction of a facility intended, at least in part, for the provision of health services, the applicant shall provide an opportunity for comment and approval with respect to such project to (1) the State agency administering or supervising the administration of the State plan approved under section 314(a) of the Act, and (2) the public or nonprofit private agency or organization responsible for the plan or plans referred to in section 314(b) of the Act and covering the area in which such project is to be located or if there is no such agency, such other public or nonprofit private agency or organization (if any) as performs, as determined in accordance with criteria of the Director, similar functions.

(e) *Clearinghouse review.* As required by OMB Circular A-95 the applicant must provide timely notice to the planning and development clearinghouse of the State and the region, if there is one, or of the metropolitan area in which the project is to be located, of its intent to apply for a grant under this part, and of the nature of the project for which assistance has been sought, including a summary description of such project. Any comments received by the applicant from the clearinghouse pursuant to such notification shall be considered by the applicant and shall be included in or attached to the application.

§ 52b.5 Evaluation.

In approving applications for construction grants under this part, the Director shall take into account, among other factors, the following: (a) The relevance of the program for which construction is proposed to the objectives and priorities of the National Cancer Program (42 U.S.C. 286a), (b) the scientific merits of the program for which construction is proposed, (c) the scientific or professional standing or reputation of the agency or institution and of its existing or proposed officers and research staff, (d) the availability, by affiliation or other association, of other scientific or health personnel and facilities to the extent necessary to carry out effectively the contemplated program, including the adequacy of an acceptable biohazard control and containment program where warranted, (e) the need to accomplish appropriate geographical distribution of facilities, and (f) the financial need of the applicant.

§ 52b.6 Other HHS regulations that apply.

Several other regulations apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50—PHS grants appeals process.

45 CFR Part 16—Department grants appeal process.

45 CFR Part 74—Administration of grants.

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates, and other cost allocations).

45 CFR Part 80—Nondiscrimination under programs receiving federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964.

45 CFR Part 81—Practice and procedure for hearings under Part 80.

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.

§ 52b.7 Rate of Federal financial participation.

(a) The amount of a construction grant may not exceed 75 percent of the necessary allowable cost of construction as determined by the Director, except that in situations where the Director finds good cause for waiving requirements, for example, in order to achieve sufficient geographical distribution of facilities, the amount of the construction grant may exceed 75 percent of the necessary allowable cost of construction.

(b) Subject to paragraph (a) of this section, the Director shall set the actual rate of Federal financial participation in the necessary allowable cost of construction taking into consideration the most effective use of available Federal funds to further the purposes of section 406(b) or section 404(b)(9).

§ 52b.8 Terms and conditions.

In addition to any other requirement imposed by law or determined by the Director to be reasonably necessary with respect to any particular grant to fulfill the purposes thereof, each construction grant shall be subject to the condition that the applicant provide certain evidences, supported by such documentation as the Director may reasonably require. The Director may for good cause shown approve exceptions to these conditions and evidences where the Director finds that such exceptions are not inconsistent with the Act and the purposes of the program:

(a) *Title.* That the applicant has a fee simple or such other estate or interest in the site, including necessary easements and rights-of-way sufficient to assure for the estimated useful life of the facility, as determined by the Director, undisturbed use and possession for the purpose of the construction and operation of the facility.

(b) *Plans and specifications.* That approval by the Director of the final working drawings and specifications will be obtained before the project is advertised or placed on the market for bidding and that such approval shall include a determination by the Director that the final plans and specifications conform to the minimum standards of construction and equipment as set forth in § 52b.11 of this part.

(c) *Relocation assistance.* That in the case of a public applicant with an approved project which involves the displacement of persons or businesses on or after January 4, 1971, the applicant will comply with the provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 ((42 U.S.C. 4601 et seq.), 84 Stat. 1984) and the applicable regulations issued thereunder (45 CFR Part 15).

(d) *Approval of changes in estimated cost.* That the applicant will not enter into any construction contract or contracts for the project or a part thereof, the cost of which is in excess of the estimated cost approved in the application for that portion of the work covered by the plans and specifications, without the prior approval of the Director.

(e) *Completion responsibility.* That the applicant will construct the project, or cause it to be constructed, to final completion in accordance with the grant application and approved plans and specifications.

(f) *Construction inspection.* That the applicant will provide and maintain competent and adequate architectural or engineering inspection at the construction site to insure that the completed work conforms with the approved plans and specifications.

(g) *Non-Federal share.* That sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility.

(h) *Funds for operation.* That sufficient funds will be available when construction is completed for effective use of the facility for the purposes for which it is being constructed.

(i) *Inspection.* That the Director and the Director's representatives shall have access at all reasonable times to work whereever it is in preparation or progress, and the contractor shall provide proper facilities for such access and inspection.

(j) *Accessibility to handicapped.* That, the facility shall be designed to comply with the Federal Accessibility Standard (41 CFR Subpart 101-19.6) as modified by other standards prescribed by the Director or the Administrator of General Services. The applicant will be responsible for conducting inspections to insure compliance with these specifications by the contractor.

(k) *Minimum standards of construction and equipment.* That the plans and specifications for the project will conform to the minimum standards of construction and equipment as set forth in § 52b.11 of this part.

[45 FR 12243, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52b.9 Acquisition of facilities.

In addition to the other requirements of this part, the following provisions are applicable to the acquisition of existing facilities.

(a) *Minimum standards of construction and equipment.* A determination by the Director that the facility conforms (or upon completion of any necessary construction will conform) to the minimum standards of construction and equipment as set forth in § 52b.11 of this part, shall be obtained before entering into a final or unconditional contract for such acquisition. Where the Director finds that exceptions to or modification of any such minimum standards of construction and equipment would be consistent with the purposes of section 406(b) or section 404(b)(9) of the Act, the Director may authorize such exceptions or modifications;

(b) *Estimated cost of acquisition and remodeling: Suitability of facility.* Each application for a project involving the acquisition of existing facilities shall include in the detailed estimates of the cost of the project, the cost of acquiring such facilities, and any cost of remodeling, renovating or altering such facilities to serve the purposes for which they are acquired. Such application shall demonstrate to the satisfaction of the Director that the architectural, structural and other pertinent features of the facility, as modified by any proposed expansion, remodeling, renovation, or alteration, will be clearly suitable for the purposes of section 406(b) or section 404(b)(9) of the Act, and, to the extent of the costs in which Federal participation is requested, are not in excess of what is necessary for the services proposed to be provided in such facilities;

(c) *Bona fide sale.* Federal participation in the acquisition of existing facilities is on condition that such acquisition constitutes a bona fide sale involving an actual cost to the applicant and will result in additional or improved facilities for purposes of section 406(b) or section 404(b)(9) of the Act; and

(d) *Facility which has previously received Federal grant.* No grant for the acquisition of a facility which has previously received a Federal grant for construction, acquisition, or equipment shall serve either to reduce or restrict the liability of the applicant or any other transferor or transferee from any obligation of accountability imposed by the Federal Government by reason of such prior grant.

[45 FR 12243, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52b.10 Additional conditions.

The Director may with respect to any grant award impose additional conditions consistent with these regulations prior to or at the time of any award when in the Director's judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of the National Cancer Program, or the conservation of grant funds.

§ 52b.11 Minimum standards of construction and equipment.

The standards set forth in this section have been determined by the Director to constitute minimum requirements for construction and equipment, including remodeling, renovation, or alteration of existing buildings, and shall apply to all projects for which Federal assistance is requested under section 406(b) or section 404(b)(9) of the Act. In accordance with 5 U.S.C. 552(a)(1), the publications to which reference is made in this section, unless otherwise indicated, are hereby incorporated by reference and made a part hereof. These documents are available for inspection at the Department and Regional Offices' Information Centers listed in 45 CFR 5.31 and copies of such documents may be purchased as specified. The Director may for good cause shown approve plans and specifications which contain deviations from the requirements prescribed, if the Director is satisfied that the purposes of such requirements have been fulfilled. In addition to these requirements, it is recognized that each project will have to meet the requirements of State and/or local codes and ordinances relating to construction.

(a) *"General".* The structural design, construction, and fire safety provisions of all project facilities shall comply with the standards of the Uniform Building Code (available from International Conference of Building Officials, 5360 South Workman Road, Whittier, California 90601) or with applicable State or local codes and ordinances, whichever is more restrictive.

(b) *"Mechanical".* All installations of fuel burning equipment, steam, heating, air conditioning and ventilation, plumbing and other piping systems, incinerators, and boilers shall comply with the following standards:

(1) Handbook of Fundamentals: American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE), United Engineer Center, 345 East 47th Street, New York, New York 10017.

(2) National Standard Plumbing Code: National Association of Plumbing-Heating-Cooling Contractors, 1016 20th Street NW., Washington, D.C. 20036.

(3) Standard for Non-Flammable Medical Gas Systems, 1973, NFPA Bulletin No. 56F, National Fire Protection Association, 470 Atlantic Avenue, Boston, Massachusetts 02110.

(4) Standard for Medical-Surgical Vacuum Systems in Hospitals, Pamphlet P-2.1: Compressed Gas Association (CGA), 500 Fifth Avenue, New York, New York 10036.

(c) *"Fire and safety"*. The fire-resistant design criteria for the facility will be governed by the criteria necessary for that portion of the facility which is subject to the most severe usage. Remodeled structures shall be upgraded, in total, unless it is feasible to isolate the improved portion of the building with fire walls and fire doors. Fire-resistant design shall be in accordance with the standards of Life Safety Code, NFPA No. 101, 1973, National Fire Protection Association, 470 Atlantic Avenue, Boston, Massachusetts 02110.

(d) *"Emergency electrical service"*. Fire alarm systems and other electrical service shall conform to the standards as specified in Life Safety Code, NFPA No. 101, 1973, National Fire Protection Association, 470 Atlantic Avenue, Boston, Massachusetts 02110.

(e) *"Electrical"*. All electrical installations and equipment shall be in accordance with State and local codes and applicable sections of National Electric Code, NFPA Bulletin No. 70, 1971, National Fire Protection Association, 470 Atlantic Avenue Boston, Massachusetts 02110.

(f) *"Radiation protection"*. All areas in which X-ray, gamma-ray, beta-ray producing and similar equipment is located shall be protected from radiation in accordance with the standards which are in the Handbook Reports No. 33 and 34: National Council on Radiation Protection (NCRP), P.O. Box 30175, Washington, D.C. 20008.

(g) *"Earthquake"*. All facilities shall be designed and constructed in accordance with the standards specified in the Uniform Building Code, 1973, International Conference of Building Officials, 5360 South Workman Mill Road, Whittier, California 90601, unless more restrictive State and local codes govern.

(h) *"Zoning"*. State and local codes shall apply.

[45 FR 12243, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

PART 52c—MINORITY BIOMEDICAL SUPPORT PROGRAM

Sec.

52c.1 Applicability.
52c.2 Definitions.
52c.3 Eligibility.
52c.4 Application.
52c.5 Grant awards.
52c.6 Expenditure of grant funds.
52c.7 Other HHS regulations that apply.
52c.8 Additional conditions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 301(c), 74 Stat. 1053 (42 U.S.C. 241(c)).

SOURCE: 45 FR 12246, Feb. 25, 1980, unless otherwise noted.

§ 52c.1 Applicability.

The regulations in this part apply to grants (under the Minority Biomedical Support Program) awarded pursuant to section 301(c) of the Public Health Service Act (42 U.S.C. 241(c)) to increase the numbers of ethnic minority faculty, students, and investigators engaged in biomedical research and to broaden the opportunities for participation in biomedical research of ethnic minority faculty, students, and investigators, by providing general support for biomedical research programs at eligible institutions.

§ 52c.2 Definitions.

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the

Department of Health and Human Services to whom the authority involved has been delegated.

(c) "Nonprofit" as applied to any institution means an institution which is a corporation or association no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

(d) "Ethnic minorities" includes but is not limited to such groups as blacks, Spanish-speaking Americans, and American Indians.

(e) "Program director" means a single individual, designated in the grant application, who is scientifically trained and has research experience and who is responsibie for the overall execution of the program supported under this part at the grantee institution.

§ 52c.3 Eligibility.

To be eligible for a grant under this Program, an applicant must be:

(a) One of the following:

(1) A public or private nonprofit university, four year college, or other institution offering undergraduate, graduate, or health professional degrees, with a traditionally high (more than 50 percent) minority student enrollment;

(2) A public or private nonprofit two year college with a traditionally high (more than 50 percent) minority student enrollment;

(3) A public or private nonprofit university, four year college, or other institution offering undergraduate, graduate, or health professional degrees, with a student enrollment a significant proportion (but not necessarily more than 50 percent) of which is derived from ethnic minorities, provided the Secretary determines that said institution has a demonstrated commitment to the special encouragement of and assistance to ethnic minority faculty, students, and investigators; or

(4) An Indian tribe which has a recognized governing body which performs substantial governmental functions, or an Alaska Regional Corporation as defined in the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*), and

(b) Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

[45 FR 12246, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52c.4 Application.

(a) Application for a grant under this subpart shall be made on an authorized form. Applicants shall submit completed forms on or before the dates the Secretary may prescribe.

(b) Each private institution, which does not already have on file with the National Institutes of Health evidence of nonprofit status, must submit with its application acceptable proof of such status.

(c) Each application shall contain a narrative description of the institution's present biomedical research program; the nature and purpose of the proposed biomedical research program; the manner in which the institution intends to conduct said program in conformity with this part; and the value of the program to the overall mission and objectives of the institution. The application shall also set forth the proposed project period (not to exceed five years), a detailed budget for the first budget period and anticipated total needs for each of the succeeding budget periods of the requested project period, a justification for the amount of grant funds requested, the names and qualifications of the program director and the directors of individual projects within the program, the total facilities and resources that will be available (including where necessary collaborative arrangements with other institutions), and such other pertinent information as the Secretary may require.

(d) An institution seeking continued support under this part at the end of a project period must submit a new application in accordance with this section.

§ 52c.5 Grant awards.

(a) Within the limits of funds available, and upon such recommendation as may be required by law, the Secretary shall award grants to those applications with proposed biomedical research programs which will, in the

Secretary's judgment, best promote the purposes of this part, taking into consideration among other pertinent factors:

(1) The benefits that can be expected to accrue to the national effort in biomedical research;

(2) The institution's capability, from a scientific and technical standpoint, to engage in biomedical research;

(3) The benefits that can be expected to accrue to the institution and its students;

(4) The administrative and managerial capability and competence of the applicant;

(5) The availability of the facilities and resources (including where necessary collaborative arrangements with other institutions) to engage in biomedical research;

(6) The applicant's relative need for funding; and

(7) The overall significance of the proposal in terms of numbers of ethnic minority persons benefited thereby.

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 1-5 years.

(c) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

[45 FR 12246, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52c.6 Expenditure of grant funds.

(a) Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

(b) The Secretary may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the Secretary's written approval is obtained. The amount of any subsequent award will take into consideration unobligated grant funds remaining in the grant account.

[45 FR 12246, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980; 45 FR 68392, Oct. 15, 1980]

§ 52c.7 Other HHS regulations that apply.

Several other regulations apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50—PHS grant appeals process

45 CFR Part 16—Department grant appeal process

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates, and other cost allocations)

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Regulation for the Administration and Enforcement of Section 704 and 855 of the PHS Act

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 FR 6724—Guidelines for Research Involving Recombinant DNA Molecules published by the National Institutes of Health

[45 FR 12246, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980; 45 FR 68392, Oct. 15, 1980]

§ 52c.8 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in the Secretary's judgment those conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

PART 52d—NATIONAL CANCER INSTITUTE CLINICAL CANCER EDUCATION PROGRAM

Sec.

52d.1 Applicability.
52d.2 Definitions.
52d.3 Eligibility.
52d.4 Application.
52d.5 Program requirements.
52d.6 Grant awards.
52d.7 Expenditure of grant funds.
52d.8 Other HHS regulations that apply.
52d.9 Additional conditions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 404(a)(4), 92 Stat. 3426 (42 USC 285).

SOURCE: 45 FR 12247, Feb. 25, 1980, unless otherwise noted.

§ 52d.1 Applicability.

The regulations in this part apply to grants under the Clinical Cancer Education Program authorized by section 404(a)(4) of the Public Health Service Act, to encourage planning and development of multidisciplinary educational programs aimed at achieving optimal care of cancer patients and to enable students in the health professions to acquire basic knowledge of neoplastic disease and the preventive measures and diagnostic and therapeutic skills necessary to the provision of such care.

§ 52d.2 Definitions.

(a) "Act" means the Public Health Service Act, as amended.

(b) "Director, NCI," means the Director of the National Cancer Institute and any other officer or employee of said Institute to whom the authority involved has been delegated.

(c) "Nonprofit" as applied to any institution means an institution which is a corporation or an association no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

(d) "Board" means the National Cancer Advisory Board established by section 407 of the Act (42 U.S.C. 286b).

(e) "Affiliated teaching hospital" means a hospital which, although not owned by such school, has a written agreement with a school of medicine, osteopathy, dentistry, or public health eligible for assistance under this part, providing for effective control by the school of the teaching in the hospital.

(f) "Specialized cancer institute" means an institution which has as its primary mission the diagnosis, prevention, or treatment of cancer.

[45 FR 12247, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52d.3 Eligibility.

To be eligible for a grant under this part an applicant must be:

(a) A public or private, nonprofit school of medicine, osteopathy, dentistry, or public health, affiliated teaching hospital, or specialized cancer institute; and

(b) Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

§ 52d.4 Application.

(a) Application for a grant under this subpart shall be made on an authorized form.[1] Applicants shall submit completed forms, on or before the dates the Director, NCI, may prescribe.

(b) Each private institution which does not already have on file with the National Institutes of Health evidence of nonprofit status, must submit with its application acceptable proof of such status.

(c) In addition to any other pertinent information that the Director,

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[1] Applications and instructions are available from the Division of Cancer Research Resources and Centers, Education Branch, Westwood Building, 5333 Westbard Avenue, Bethesda, Maryland 20205.

NCI, may require, each application shall set forth in detail:

(1) A program plan defining the objectives of the proposed program and the means by which these objectives would be achieved, including descriptions of:

(i) The general educational level (e.g., pre-doctoral, post-doctoral) of the students to be involved in the program;

(ii) The proposed course of study and its relation to the diagnosis, prevention, control, and treatment of cancer;

(iii) The clinical experiences to be provided to the students;

(iv) Multidisciplinary aspects of the program;

(v) The particular schools or branches within the institution which would have responsibility for individual aspects of the program; and

(vi) The teaching mechanisms to be employed, including specific discussion of those techniques which would be innovative.

(2) The availability of personnel, facilities, and resources needed to carry out the program;

(3) The names, qualifications, and proposed duties of the program director and any staff members who would be responsible for the program, including a description of those duties which would actually be carried out by the program director and those which would be shared with or assigned to others;

(4) The names and qualifications of proposed members of a cancer education committee which would be established by the applicant to advise it on the planning, organization, operation and evaluation of the program and the specific duties which would be assigned to said committee;

(5) Insofar as necessary, cooperative arrangements with other schools, hospitals, and institutions which would participate in the program;

(6) The proposed project period, a detailed budget for the first budget period including a list of other anticipated sources of support and anticipated total needs for each of the succeeding budget periods of the requested project period, and a justification for the amount of grant funds requested;

(7) Proposed methods for monitoring and evaluating the program; and

(8) A description of how the education and training effort will be sustained upon expiration of the award.

§ 52d.5 Program requirements.

(a) If the program is to be offered at the graduate level, it must be multidisciplinary in scope involving at least two or more clinical or preclinical sciences relating to cancer;

(b) The cancer education committee provided for in the approved application must meet at least four times per year, and must be chaired by the program director.

§ 52d.6 Grant awards.

(a) Within the limits of funds available, after consultation with the Board, the Director, NCI, may award grants to applicants with proposed programs which in the NCI Director's judgment best promote the purposes of this part, taking into consideration among other pertinent factors:

(1) The relevance of the proposed program to the objectives of this part;

(2) The extent to which the program would involve innovative teaching techniques;

(3) The availability of adequate staff, facilities, and resources (including where necessary cooperative arrangements with other institutions or hospitals) to carry out the program;

(4) The qualifications and experience of the program director;

(5) The authority of the program director to ensure that the program is planned with multidisciplinary input and that multidisciplinary aspects of the program are carried out;

(6) The extent to which the cancer education committee is broadly representative of the disciplines concerned with cancer care and teaching and is allowed to participate in the planning, organization, operation, and evaluation of the program;

(7) If the program is to be offered at the pre-doctoral level, the extent to which its objectives are designed to aid students:

(i) To acquire a basic understanding of fundamental principles of cancer biology, epidemiology, detection, diagnosis, prevention, treatment and control;

(ii) To interest students in learning more about cancer; and

(iii) To develop an appreciation of the need for a comprehensive multidisciplinary approach to the care of cancer patients;

(8) The administrative and managerial capability of the applicant;

(9) The reasonableness of the proposed budget in relation to the proposed program;

(10) The adequacy of the methods for monitoring and evaluating the program on a continuing basis; and

(11) The degree to which the application adequately provides for the requirements set forth in § 52d.5.

(b) The notice of grant award specifies how long HHS intends to support the program without requiring the program to recompete for funds. This period, called the project period, will usually be for 1-5 years.

(c) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 52d.7 Expenditure of grant funds.

(a) Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the awards, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74, except that grant funds may not be used for costs incurred in connection with activities which, prior to the grant, were part of the grantee's standard curriculum.

(b) The Director, NCI, may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the NCI Director's written approval is obtained. The amount of any subsequent award will take into consideration unobligated grant funds remaining in the grant account.

§ 52d.8 Other HHS regulations that apply.

Several other regulations apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50—PHS grant appeals process

45 CFR Part 16—Department grant appeal process

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedure (indirect cost rates, and other cost allocations)

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Regulation for the Administration and Enforcement of Sections 704 and 855 of the PHS Act

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from federal financial assistance

[45 FR 12247, Feb. 25, 1980; 45 FR 20097, Mar. 27, 1980]

§ 52d.9 Additional conditions.

The Director, NCI, may with respect to any grant award impose additional conditions prior to or at the time of any award when in the NCI Director's judgment those conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

PART 52e—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE GRANTS FOR PREVENTION AND CONTROL PROJECTS

Sec.
52e.1 Applicability.
52e.2 Definitions.
52e.3 Eligibility.
52e.4 Application.
52e.5 Project requirements.
52e.6 Grant awards.
52e.7 Expenditure of grant funds.
52e.8 Other HHS regulations that apply.
52e.9 Additional conditions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 414, 86 Stat. 682 (42 U.S.C. 287c).

SOURCE: 45 FR 12249, Feb. 25, 1980, unless otherwise noted.

§ 52e.1 Applicability.

(a) The regulations in this part apply to grants under section 414 of the Public Health Service Act (42 U.S.C. 287c) for projects: (1) To demonstrate and evaluate the effectiveness of new techniques or procedures for the prevention, diagnosis, or treatment of heart, blood vessel, lung, and blood diseases, (2) to develop and evaluate methods of educating health practitioners concerning the prevention and control of these diseases, and (3) to develop and evaluate methods of educating the public concerning the prevention and control of these diseases.

(b) For purposes of this part, treatment may include emergency medical services.

[45 FR 12249, Feb. 25, 1980; 45 FR 20097, Mar. 27, 1980]

§ 52e.2 Definitions.

As used in this part:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Director, NHLBI," means the Director of the National Heart, Lung, and Blood Institute and any other officer or employee of said Institute to whom the authority involved has been delegated.

(c) "Nonprofit" as applied to any agency or institution means an agency or institution which is a corporation or an association no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

(d) "Council" means the National Heart, Lung, and Blood Advisory Council, established by section 417(a) of the Act (42 U.S.C. 287f(a)).

(e) "National Program" means the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program referred to in section 413 of the Act (42 U.S.C. 287b).[3]

(f) "Emergency medical services" means the services utilized in responding to the perceived individual need for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury.

52e.3 Eligibility.

To be eligible for a grant under this part, an applicant must be a public or nonprofit private agency or institution.

52e.4 Application.

(a) Application for a grant under this subpart shall be made on an authorized form.[4] Applicants shall submit completed forms on or before the dates the Director, NHLBI, may prescribe.

(b) Each private institution which does not already have on file with the National Institutes of Health evidence of nonprofit status, must submit with its application acceptable proof of such status.

(c) In addition to any other pertinent information that the Director, NHLBI, may require each application shall set forth in detail:

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[3] Single copies of the National Program are available upon request from the Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20205.

[4] Applications and instructions are available from the Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20205.

(1) The nature and purpose of the proposed project and the methods to be employed in carrying it out;

(2) The relevance of the proposed project to the National Program;

(3) The defined population to participate in the proposed project and the rationale for its selection;

(4) With respect to applications relating to projects covered by § 52e.1(a)(1), prior research findings on which the proposed project is based;

(5) The personnel, facilities, and other resources, including community resources, available to carry out the proposed project;

(6) Current activities of the applicant involving prevention or control of heart, blood vessel, lung, and blood diseases, the sources of funding for such activities, and the anticipated relationship of these activities to the proposed project;

(7) The names and qualifications of the project director and key staff members who would be responsible for conducting the proposed project;

(8) Proposed methods for monitoring and evaluating the project; and

(9) The proposed project period; a detailed budget for the first budget period, including a list of other anticipated sources of support and anticipated total needs for each of the succeeding budget periods of the requested project period; and a justification for the amount of grant funds requested.

§ 52e.5 Project requirements.

(a) An approvable application must demonstrate to the satisfaction of the Director, NHLBI, that:

(1) With respect to applications relating to projects covered by § 52e.1(a)(1), the techniques or procedures to be demonstrated and evaluated have been found safe and effective in the research setting and, based upon research findings, appear to have the potential for general applicability to the prevention, diagnosis, or treatment of heart, blood vessel, lung, or blood diseases;

(2) With respect to applications relating to projects covered by § 52e.1(a)(2) and § 52e.1(a)(3), the project will include development and evaluation of one or more methods for educating health practitioners or the public concerning advances in the prevention, diagnosis, or treatment of such diseases; and

(3) The nature of the project is such that its completion may be anticipated within the project period, or such other period as may be specified in the application.

(b) The project must, in the judgment of the Director, NHLBI, be necessary for cooperation by the National Heart, Lung, and Blood Institute with one or more other Federal Health agencies, State, local or regional public health agencies, or nonprofit private health agencies in the diagnosis, prevention, or treatment of heart, blood vessel, lung or blood diseases.

§ 52e.6 Grant awards.

(a) Within the limits of funds available, after consultation with the Council, the Director, NHLBI, may award grants to applicants with proposed projects which in the NHLBI Director's judgment best promote the purposes of section 414 of the Act, taking into consideration among other pertinent factors:

(1) The scientific and technical merit of the proposed project;

(2) The significance of the project in relation to the goals of the National Program;

(3) Whether the project appropriately emphasizes the prevention, diagnosis, or treatment of heart, blood vessel, lung, or blood diseases of children;

(4) The qualifications and experience of the project director and other key personnel;

(5) The administrative and managerial capability and fiscal responsibility of the applicant;

(6) The reasonableness of the proposed budget in relation to the proposed project;

(7) The adequacy of the methods proposed for monitoring and evaluating the proposed project; and

(8) The degree to which the application adequately provides for the requirements set forth in §§ 52e.5(a) and 52e.5(b).

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 1-5 years.

(c) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(e) Any funds granted under this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms, and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

§ 52e.7 Expenditure of grant funds.

(a) Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

(b) The Director, NHLBI, may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the NHLBI Director's written approval is obtained. The amount of any subsequent award will take into consideration unobligated grant funds remaining in the grant account.

§ 52e.8 Other HHS regulations that apply.

Several other regulations apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50—PHS grant appeals process

45 CFR Part 16—Department grant appeal process

45 CFR Part 46—Protection of human subjects

45 CFR P-rt 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates, and other cost allocations)

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Regulation for the Administration and Enforcement of Sections 704 and 855 of the PHS Act

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs or activities receiving or benefiting from federal financial assistance

[45 FR 12249, Feb. 25, 1980; 45 FR 20097, Mar. 27, 1980]

§ 52e.9 Additional conditions.

The Director, NHLBI, may with respect to any grant award impose additional conditions prior to or at the time of any award when in the NHLBI Director's judgment those conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

PART 52h—SCIENTIFIC PEER REVIEW OF RESEARCH GRANT APPLICATIONS AND RESEARCH AND DEVELOPMENT CONTRACT PROJECTS

Sec.
52h.1 Applicability.
52h.2 Definitions.
52h.3 Establishment and operation of peer review groups.
52h.4 Composition of peer review groups.
52h.5 Conflict of interest.
52h.6 Availability of information.

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52h.7 Grants; matters to be reviewed.
52h.8 Grants; review criteria.
52h.9 Unsolicited contract proposals; matters to be reviewed.
52h.10 Contract projects involving solicited contract proposals; matters to be reviewed.
52h.11 Contract projects and proposals; review criteria.
52h.12 Applicability of other regulations.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351 (42 U.S.C. 289*l*-4), unless otherwise noted.

SOURCE: 43 FR 7862, Feb. 24, 1978, unless otherwise noted.

§ 52h.1 Applicability.

The regulations in this part apply to:

(a) Applications for grants for biomedical and behavioral research, under the Act to the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Health Resources Adminstration. These regulations do not apply to applications for:

(1) Continuation funding for budget periods within an approved project period;

(2) Supplemental funding to meet increased administrative costs within a project period; or

(3) Construction grants.

(b) Biomedical and behavioral research and development contract projects administered by the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Health Resources Administration.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 289*l*-4))

[45 FR 35328, May 27, 1980]

§ 52h.2 Definitions.

As used in this part:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Project period" has the same meaning as in 42 CFR Part 52.

(c) "Budget period" means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(d) "Awarding official" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated; *Except that,* where the Act specifically authorizes another official to make awards in connection with a particular program, the "awarding official" shall mean said other official and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(e) "Peer review group" means a group of experts qualified by training and experience in particular scientific or technical fields to give expert advice, in accordance with the provisions of this part, on the scientific and technical merit of grant applications or contract projects in those fields.

(f) "Research" means systematic study directed toward new or fuller knowledge and understanding of the subject studied.

(g) "Development" means the systematic use of knowledge and understanding gained from research, directed toward creating useful materials, devices, systems, or methods.

(h) "Research and development contract project" means an identified, circumscribed activity, involving a single contract or two or more similar, related, or interdependent contracts, intended and designed to acquire new or fuller knowledge and understanding of a subject and/or to use such knowledge and understanding to develop useful materials, devices, systems, or methods. The terms include (but are not limited to) development and utilization of resources, testing, demonstrations, clinical trials, preparation of reports, and production of experimental or test models necessary or incidental to a research and/or development activity, but exclude quantity production and routine product testing and quality control.

(i) "Project concept" means the basic purpose, scope, and objectives of the project.

(j) "Project approach" means the methodology to be followed and the resources needed in carrying out the project.

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(k) "Contract proposal" means a written offer to enter into a contract, submitted to an awarding official by an individual or non-Federal organization, and including as a minimum a description of the nature, purpose, duration, and cost of the project and the methods, personnel, and facilities to be utilized in carrying it out.

(l) "Solicited contract proposal" has the same meaning as in 41 CFR 3-1.353(b)(2).

(m) "Unsolicited contract proposal" has the same meaning as in 41 CFR 3-4.5201.

(n) "Request for Proposals" means a Government solicitation to prospective offerors, under procedures for negotiated contracts, to submit a proposal to fulfill specific agency requirements based on terms and conditions defined in the request for proposals. The request for proposals contains information sufficient to enable all offerors to prepare competitive proposals, and is as complete as possible with respect to: Nature of work to be performed; descriptions and specifications of items to be delivered; performance schedule; special requirements clauses, or other circumstances affecting the contract; format for cost proposals; and evaluation criteria by which the proposals will be evaluated.

§ 52h.3 Establishment and operation of peer review groups.

(a) To the extent applicable, the Federal Advisory Committee Act (5 U.S.C. App. I), Department of Health and Human Services (45 CFR Part 11), implementing regulations and Chapter 9 of the Department of Health and Human Services General Administration Manual[1] will govern the establishment and operation of peer review groups, including that meetings shall be open to the public except as determined by the Secretary.

(b) Subject to § 52h.5 and paragraph (a) of this section, the Director of the National Institutes of Health; the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration; and the Administrator, Health Resources Administration will adopt procedures for the conduct of reviews and the formulation of recommendations under §§ 52h.7, 52h.9 and 52h.10 within their respective agencies.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 289*l*-4))

[43 FR 7862, Feb. 24, 1978, as amended at 45 FR 35328, May 27, 1980]

§ 52h.4 Composition of peer review groups.

(a) To the extent applicable, the selection and appointment of members of peer review groups and their terms of service will be governed by Chapter 9 of the Department of Health and Human Services General Administration Manual.[1]

(b) Subject to paragraph (a) of this section, members will be selected based upon their training and experience in relevant scientific or technical fields, taking into account, among other factors:

(1) The level of formal scientific or technical education completed or experience acquired by the individual;

(2) The extent to which the individual has engaged in relevant research, the capacities (e.g., principal investigator, assistant) in which the individual has done so, and the quality of such research;

(3) Recognition as reflected by awards and other honors received from scientific and professional organizations outside the Department of Health and Human Services; and

(4) The need for the group to have included within its membership experts from various areas of specialization within relevant scientific or technical fields.

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[1] The Department of Health and Human Services General Administration Manual is available for public inspection and copying at the Department's and Regional Offices' information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Printing Office, Washington, D.C. 20402.

(c) Not more than one-fourth of the members of any peer review group to which these regulations are applicable may be officers or employees of the United States. For purposes of the preceding sentence, membership on such groups does not make an individual an officer or employee of the United States.

§ 52h.5 Conflict of interest.

(a) Members of peer review groups covered by this part are subject to relevant provisions in Title 18 of the United States Code, relating to criminal activity, the Department of Health and Human Services Standards of Conduct (45 CFR Part 73), and Executive Order 11222, as amended.

(b) In addition to any restrictions imposed under paragraph (a) of this section:

(1) No member of a peer review group may participate in or be present during any review by said group of a grant application, contract project, or contract proposal in which, to the member's knowledge, any of the following has a financial interest: (i) The member or his or her spouse, parent, child, or partner, (ii) any organization in which the member or his or her spouse, parent, child, or partner is serving as an officer, director, trustee, partner, or employee, or is otherwise similarly associated, or (iii) any organization with which the member or his or her spouse, parent, child, or partner is negotiating or has any arrangement concerning prospective employment or other similar association.

(2) In the event any member of a peer review group or his or her spouse, parent, child, or partner is currently or expected to be the principal investigator or member of the staff responsible for carrying out any research or development activities contemplated as part of a grant application, contract project, or contract proposal, that group is disqualified and the review will be conducted by another group with the expertise to do so. If there is no other group with the requisite expertise, the review will be conducted by an ad hoc group no more than 50 percent of whose members may be from the disqualified group. The composition of any such ad hoc group will be determined in accordance with § 52h.4(b) and § 52h.4(c) of this part and, to the extent feasible, § 52h.4(a) of this part.

(3) Where a member of a peer review group participates in or is present during:

(i) Development or review of a project approach or request for proposals by said group or

(ii) Review by said group under § 52h.10(b) or § 52h.10(c), i.e. after the issuance of a request for proposals, no contract may thereafter be awarded as the result of such development or review to said member, his or her spouse, parent, child, or partner or any organization in which the member, his or her spouse, parent, child, or partner was serving as officer, director, trustee, partner, or employee at the time of such development or review or with which the member, his or her spouse, parent, child, or partner was negotiating or had any arrangement concerning prospective employment at said time.

(4) No member of a peer review group may participate in any review under this part of a specific grant application or contract project for which the member has had or is expected to have any other responsibility or involvement (whether preaward or postaward) as an officer or employee of the United States.

(c) Where permissible under the statutes, standards, and order cited in paragraph (a) of this section, the Director of the National Institutes of Health; the Administrator of the Alcohol, Drug Abuse and Mental Health Administration; the Administrator of the Health Resources Administration; or their designees may waive the requirements in paragraph (b) of this section if he or she determines that there is no other practical means for securing appropriate expert advice on a particular grant application, contract project, or contract proposal.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 315, 92 Stat. 3436 (42 U.S.C. 289*l*-4))

[43 FR 7862, Feb. 24, 1978, as amended at 45 FR 35328, May 27, 1980]

§ 52h.6 Availability of information.

Transcripts, minutes, and other documents made available to or prepared for or by a peer review group will be available for public inspection and copying to the extent provided in the Freedom of Information Act (5 U.S.C. 552), the Federal Advisory Committee Act (5 U.S.C. App. I), the Privacy Act (5 U.S.C. 552a), and implementing Department of Health and Human Services regulations (45 CFR Parts 5, 5b).

§ 52h.7 Grants; matters to be reviewed.

(a) No awarding official will make a grant based upon an application covered by this part unless the application has been reviewed by a peer review group in accordance with the provisions of this part and said group has made recommendations concerning the scientific merit of such application. In addition, where under applicable law an awarding official is required to secure the approval or advice of a national advisory council or board concerning an application, said application will not be considered by the council or board unless it has been reviewed by a peer review group in accordance with the provisions of this part and said group has made recommendations concerning the scientific merit of the application except where the council or board is the peer review group.

(b) Except to the extent otherwise provided for by law, such recommendations are advisory only and not binding on the awarding official or national advisory council or board.

§ 52h.8 Grants; review criteria.

In carrying out its review under § 52h.7, the peer review group will take into account, among other factors:

(a) The significance and originality from a scientific or technical standpoint of the goals of the proposed research;

(b) The adequacy of the methodology proposed to carry out the research;

(c) The qualifications and experience of the principal investigator and proposed staff;

(d) The reasonable availability of resources necessary to the research;

(e) The reasonableness of the proposed budget and duration in relation to the proposed research; and

(f) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects.

§ 52h.9 Unsolicited contract proposals; matters to be reviewed.

(a) No awarding official will award a contract based upon an unsolicited contract proposal covered by this part unless the proposal has been reviewed by a peer review group in accordance with the provisions of this part (pursuant to procedures set forth in 41 CFR Subpart 3-4.52) and said group has made recommendations concerning the scientific merit of such proposal.

(b) Except to the extent otherwise provided for by law, such recommendations are advisory only and not binding on the awarding official.

52h.10 Contract projects involving solicited contract proposals; matters to be reviewed.

(a) Subject to paragraph (b) of this section, no awarding official will issue a request for contract proposals with respect to a contract project involving solicited contract proposals unless the project concept has been reviewed by a peer review group in accordance with the provisions of this part and said group has made recommendations concerning the scientific merit of said concept. Where in the judgment of the awarding official the project approach has been sufficiently well defined by the time the review required by the preceding sentence is conducted, this review and the resulting recommendations shall include the project approach as well.

(b) The awarding official may waive the requirements of paragraph (a) of this section for peer review before issuing a request for contract proposals if he determines that the accomplishments of essential program objectives would otherwise be placed in jeopardy and any further delay would clearly not be in the best interest of the Government. The awarding official shall specify in writing the grounds on which this determination is based. Under such circumstances, the awarding official will not award a contract based on the request for contract proposals unless the proposals received in response to the request have been reviewed by a peer review group and that group has made recommendations concerning the scientific merit of the project concept and of the approaches outlined in the proposals. The request for proposals will indicate that the project concept has not been reviewed by a peer review group and that no award will be made until such review is conducted and recommendations made based on such review.

(c) The Director of the National Institutes of Health; the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration; the Administrator of the Health Resources Administration; or their designees may identify individual contracts or classes of contracts which may not be awarded unless all pertinent contract proposals have been reviewed by a peer review group in accordance with the provisions of this part and that group has made recommendations concerning the scientific merit of the proposals.

(d) Except to the extent otherwise provided for by law, such recommendations are advisory only and not binding on the awarding official.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 315, 92 Stat. 3436 (42 U.S.C. 289*l*-4))

[43 FR 7862, Feb. 24, 1978, as amended at 45 FR 35328, May 27, 1980]

§ 52h.11 Contract projects and proposals; review criteria.

(a) In carrying out its review of a project concept under § 52h.10(a) or § 52h.10(b), the peer review group will take into account, among other factors:

(1) The significance from a scientific or technical standpoint of the goals of the proposed research or development activity;

(2) The availability of the technology and other resources necessary to achieve these goals;

(3) The extent to which there are identified, practical uses for the anticipated results of the activity; and

(4) Where the review includes the project approach, the adequacy of the methodology to be utilized in carrying out the activity.

(b) In carrying out its review of unsolicited contract proposals under § 52h.9, the peer review group will take into account, among other factors, those criteria in § 52h.8 which are relevant to the particular proposals.

(c) In carrying out its review of solicited contract proposals under § 52h.10(c) the peer review group will evaluate each proposal in accordance with the criteria set forth in the request for proposals.

§ 52h.12 Applicability of other regulations.

The regulations in this part are in addition to, and do not supersede other regulations concerning grant applications, contract projects, or contract proposals appearing elsewhere in this Title, Title 41, or Title 45 of the Code of Federal Regulations

PART 53—GRANTS, LOANS AND LOAN GUARANTEES FOR CONSTRUCTION AND MODERNIZATION OF HOSPITALS AND MEDICAL FACILITIES

Subparts A-K—[Reserved]

Subpart L—Services for Persons Unable to Pay; Community Service; Nondiscrimination

Sec.
53.111 Services for persons unable to pay.
53.112 Nondiscrimination.
53.113 Community service.

Subpart M—Methods of Administration of the State Plan

53.134 Notice of change of status of facility.
53.135 Good cause for other use of facility.

Subpart N—Loan Guarantees and Direct Loans

53.154 Waiver of right of recovery.

AUTHORITY: Sections 215, 603, 609, 623 of the Public Health Service Act as amended, 58 Stat. 690, 78 Stat. 451 and 456, 84 Stat. 346, (42 U.S.C. 216, 291c, 291i, 291j-3).

SOURCE: 37 FR 182, Jan. 6, 1972, unless otherwise noted.

Subparts A-K—[Reserved]

Subpart L—Services for Persons Unable to Pay; Community Service; Nondiscrimination.

§ 53.111 Services for persons unable to pay.

(a) *Applicability.* The provisions of this section apply to every applicant which heretofore has given or hereafter will give an assurance that it will make available a reasonable volume of services to persons unable to pay therefor but shall not apply to an applicant (1) for more than 20 years after the completion of construction of any facility with respect to which funds have been paid under section 606 of the Act or (2) beyond the period during which any amount of a direct loan made under sections 610 or 623 of the Act, or any amount of a loan with respect to which a loan guarantee and interest subsidy has been provided under sections 623 and 624 of the Act remains unpaid.

(b) *Definitions.* As used in this section:

(1) The term "facility" includes hospitals, facilities for long-term care, outpatient facilities, rehabilitation facilities, and public health centers;

(2) The term "applicant" means an applicant for, or recipient of, a grant, a loan guarantee or a loan under the Act;

(3) "Fiscal year" means the fiscal year of the applicant;

(4) The term "operating costs" means the actual operating costs of the applicant for a fiscal year as determined in accordance with cost determination principles and requirements under Title XVIII of the Social Security Act (42 U.S.C. 1395): *Provided,* That such "operating costs" shall be determined for the applicant's entire facility and for all patients regardless of the source of payment for such care: *And provided further,* That in determining such operating costs there shall be deducted the amount of all actual or estimated reimbursements, as applicable, for services received or to be received pursuant to Title XVIII and XIX of the Social Security Act (42 U.S.C. 1395 and 1936);

(5) The term "reasonable cost" means the cost of providing services to a specific patient determined in accordance with the cost determination principles and requirements under title XVIII of the Social Security Act (42 U.S.C. 1395) and Subpart D of the regulations thereunder (20 CFR 405,[1] 401 et seq.);

(6) The term "uncompensated services" means services which are made available to persons unable to pay therefor without charge or at a charge which is less than the reasonable cost of such services. The level of such services is measured by the difference between the amount charged such persons for such services and the reasonable cost thereof;

(7) "Reasonable volume of services to persons unable to pay therefor" means a level of uncompensated services which meets a need for such services in the area served by an applicant and which is within the financial ability of such applicant to provide.

(c) *Assurance.* (1) Before an application under this part is recommended by a State agency to the Secretary for approval, the State agency shall obtain an assurance from the applicant that there will be made available in the facility or portion thereof to be constructed or modernized a reasonable volume of services to persons unable to pay therefor. The requirement of an assurance from an applicant shall be waived if the applicant demonstrates to the satisfaction of the State agency, subject to subsequent approval by the Secretary, that such a requirement is not feasible from a financial viewpoint.

(2) Prior to recommending that such requirement be waived, the State agency shall publish in a newspaper of general circulation in the area served by the applicant a notice of the request for such waiver and invite public comment thereon, allowing not less than 30 days therefor. All comments received shall be available for public inspection, and shall be considered by

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[1] Redesignated as 42 CFR Part 405 at 42 FR 52826, Sept. 30, 1977.

the State agency in arriving at its recommendation. Notice of the determination on the request for waiver shall be given to all interested persons and to the public before the approval of the Secretary is sought.

(d) *Presumptive compliance guideline.* An applicant which, for a fiscal year, (1) budgets for the support of, and makes available on request, uncompensated services at a level not less than the lesser of 3 percent of operating costs or 10 percent of all Federal assistance provided to or on behalf of the applicant under the Act, or (2) certifies that it will not exclude any person from admission on the ground that such person is unable to pay for needed services and that it will make available to each person so admitted services provided by the facility without charge or at a charge below reasonable cost which does not exceed any such person's ability to pay therefor as determined in accordance with criteria established pursuant to paragraph (g), shall be deemed in presumptive compliance with its assurance. In the case of a loan guarantee with interest subsidy or a direct loan guarantee be sold by the Secretary with an interest subsidy, the amount of Federal assistance shall include the total amount of the interest subsidy which the Secretary is, or will be, obligated to pay over the full life of the loan, as well as any other payments which the Secretary makes on behalf of the applicant in connection with the loan guarantee or the direct loan which has been sold.

(e) *Compliance reports.* (1) Each applicant shall, not later than 120 days after the end of a fiscal year, unless a longer period is approved by the State agency for good cause shown, file with the State agency a copy of its annual statement for such year as required by section 646 of the Act and § 53.128(q), which shall set forth its operating costs.

(2) With respect to each fiscal year for which a level of uncompensated services has been established in accordance with this section, the annual statement shall also set forth the amount of uncompensated services provided in such year.

(i) The provision of a level of uncompensated services in such year which equals or exceeds the level established pursuant to paragraph (h) of this section for such year shall constitute compliance with the assurance.

(ii) If the level of services provided was less than the level of uncompensated services established pursuant to paragraph (h) of this section, the applicant shall submit with such statement: A justification therefor, showing that the provision of such lower level of uncompensated services was reasonable under the circumstances; and a description of the steps it proposes to take to assure the availability and utilization of the level of uncompensated services to be established for the current fiscal year, which shall include an affirmative action plan, utilizing press releases or other appropriate means as the facility may desire to bring to the attention of the public the availability of such uncompensated services and the conditions of eligibility therefor.

(3) Each applicant shall file with its annual statement a copy of that portion of its adopted budget for the current fiscal year relating to the support of uncompensated services in such year. Such budget for uncompensated services shall be based on the operating costs of the applicant for the preceding fiscal year and shall give due cognizance to probable increases in operating costs. Except in the case of a certification pursuant to paragraph (d)(2) of this section, if the budget statement does not conform to the presumptive compliance guideline, the applicant shall submit with its statement.

(i) A justification therefor, showing that such lower level of uncompensated services is reasonable under the circumstances, and

(ii) A plan to increase such uncompensated services to meet the presumptive compliance guideline or such other level of uncompensated services as may have been established or as it requests the State agency to establish in accordance with paragraph (h) of this section.

(4) The applicant shall also submit such additional reports related to com-

pliance with its assurance as the State agency may reasonably require.

(5) Pending the establishment of a level of uncompensated services for any fiscal year pursuant to paragraph (h) of this section, the applicant shall, in such fiscal year, provide a level of services which is the higher of

(i) The level established for the preceding fiscal year (or if no such level has been established for such prior year, the level of services provided in such year) or

(ii) The level proposed in its adopted budget for the current fiscal year.

(f) *Qualifying services.* (1) In determining the amount of uncompensated services provided by an applicant, there shall be included only those services provided to an individual with respect to whom the applicant has made a written determination prior to the provision of such services that such individual is unable to pay therefor under the criteria established pursuant to 42 CFR 53.111(g), except that:

(i) Such determination may be made after the provision of such services in the case of services provided on an emergency basis: *Provided,* That when billing is made for such service, such billing must be accompanied by substantially the information required in the posted notice under paragraph (i) of this section; and

(ii) Such determination may be made after the provision of such services in the case of a change in circumstances as a result of the illness or injury occasioning such services (e.g., the patient's financial condition has changed due to a loss of wages resulting from the illness) or in case of insurance coverage or other resources being less than anticipated or the costs of services being greater than anticipated. *Further,* in all cases where such determination was not made prior to the provision of services, such services may not be included as uncompensated services if any collection effort has been made other than the rendering of bills permissible in the above exceptions: *Provided,* That such a determination may be made at any time if the determination was hindered or delayed by reason of erroneous or incomplete information furnished by or in behalf of the patient.

(2) There shall be excluded from the computation of uncompensated services:

(i) Any amount which the applicant has received, or is entitled to receive, from a third party insurer or under a governmental program; and

(ii) The reasonable cost of any services for which payment in whole or in part would be available under a governmental program (e.g., Medicare and Medicaid) in which the applicant, although eligible to do so, does not participate, but only to the extent of such otherwise available payment.

(g) *Persons unable to pay for services.* (1) The State agency shall set forth in its State plan, subject to approval by the Secretary, criteria for identifying persons unable to pay for services, which shall include persons who are otherwise self-supporting but unable to pay the full charge for needed services. Such criteria shall be based on the following or similar factors:

(i) The health and medical care insurance coverage, personal or family income, the size of the patient's family, and other financial obligations and resources of the patient or the family in relation to the reasonable cost of the services;

(ii) Generally recognized standards of need such as:

(*a*) The State standard for the medically needy as determined for the purposes of the Aid for Families with Dependent Children program;

(*b*) The current Social Security Administration poverty income level;

(*c*) The current Office of Economic Opportunity Income Poverty Guidelines applicable in the area; or

(iii) Any other equivalent measures which are found by the Secretary to provide a reasonable basis for determining an individual's ability to pay for medical and hospital services.

(2) A copy of such criteria shall be provided by the applicant, upon request, to any patient or former patient of the applicant and to any person seeking services from the applicant.

(3) The State agency shall provide a copy of such criteria to any person requesting it.

(h) *Level of uncompensated services.* (1) The State agency shall set forth in its State plan procedures for the determination for each applicant of the level of uncompensated services which constitutes a reasonable volume of services to persons unable to pay therefor provided that in no event shall the level of uncompensated services established under this section exceed the presumptive compliance guideline.

(2) The State agency shall for the purpose of making such determination, review, and evaluate the annual statement, the budget and the related documents submitted by each applicant pursuant to paragraph (e) of this section, by applying the following criteria:

(i) The financial status of the applicant, taking account of income from all sources, and its financial ability to provide uncompensated services;

(ii) The nature and quantity of services provided by the applicant;

(iii) The need within the area served by the applicant for the provision, without charge or at charge which is less than reasonable cost, for services of the nature provided or to be provided by the applicant; and

(iv) The extent and nature of joint or cooperative programs with other facilities for the provision of uncompensated services, and the extent and nature of outreach services directed to the needs of underserved areas.

(3) In accordance with its findings made after such review and evaluation, the State agency shall, within 60 days after receipt of the annual statement and related documents required by paragraph (e) of this section, for each fiscal year of an applicant which begins following the expiration of 90 days after the effective date of this regulation:

(i) Establish a level of uncompensated services for each applicant which may be equal to or less than the presumptive compliance guideline: *Provided,* That if the State agency determines, in accordance with paragraph (h)(2) of this section, that (*a*) there is a need in the area served by an applicant for a level of uncompensated services greater than the level proposed in the applicant's budget statement, and (*b*) the applicant is financially able to provide such greater level of uncompensated services, the State agency shall establish such greater level as the level applicable to the applicant; and

(ii) Accept or modify a plan submitted pursuant to paragraph (e) of this section.

(4) The State agency shall notify the applicant in writing of the level of uncompensated services which it has established for the applicant for the fiscal year. At the time of notifying the applicant, the State agency shall also publish as a public notice in a newspaper of general circulation within the community served by the applicant the rate that has been established and a statement that the documents upon which the agency based its determination are available for public inspection at a location and time prescribed. In the case of the establishment by the State agency of a rate which is less than the presumptive compliance guideline, such notice shall also include a statement that persons wishing to object to the rate established may do so by writing to the State agency within 20 days after publication of the notice: *Provided,* That the applicant may object to any level established which is greater than the level proposed in the applicant's budget statement.

(5) In accordance with the provisions of paragraph (h)(4) of this section, the applicant or any person or persons residing or located within the area served by the applicant, or any organization on behalf of such person or persons, may submit to the State agency within 20 days of the publication and sending of the notice objections to the rate established by the State agency for the applicant. Such objections may be supported in writing by factual information and argument. The State agency shall give public notice of receipt of the objections and shall make the objections and their supporting documents available for public inspection and comment. It may, if it believes that determination of the objections will be assisted by oral evidence or by oral argument, set a public hearing on the objections and shall give notice of such hearing to all interested

parties and to the public. The State agency shall within 60 days of the expiration of the period within which objections may be filed, rule upon the objections in writing, stating its reason for sustaining or overruling them, in whole or in part, and establishing finally the rate of uncompensated services either the same as, above, or below the rate previously established, as may best accord with all of the evidence on file with or heard by the State agency. Notice of the final determination shall be mailed to all parties who filed objections or who participated in the proceedings leading to the redetermination.

(6) Within 20 days of receipt of written notice of the final determination of a State agency after ruling on objections to the rate established by the State agency, the applicant or any other interested person or organization may submit to the Secretary a written request for review of the State agency determination. Such review shall be made upon the record of the State agency determination which shall be sustained if supported by substantial evidence and is not otherwise arbitrary or capricious. If the Secretary or his designee determines that the rate established by the State agency is unsupported by the evidence in the record or is otherwise arbitrary or capricious, the Secretary or his designee shall, upon the basis of the record or upon other evidence or information which is before him or which he may obtain, establish a level of uncompensated services which he determines, in accordance with the criteria set out in paragraph (h)(2) of this section, is appropriate.

(7) The level of uncompensated services established for an applicant under this section for any fiscal year shall constitute a reasonable volume of services to persons unable to pay therefor with respect to such applicant for such fiscal year.

(i) *Posted notice.* The applicant shall post notice (which shall be multilingual where the applicant serves a multilingual community), in substantially the following form, in appropriate areas within the facility (admissions, office, emergency department and business office) for the purpose of informing patients or potential patients that criteria for eligibility and applications are available upon request:

"NOTICE OF HILL-BURTON OBLIGATION

"This hospital (or other facility) is required by law to give a a reasonable amount of service at no cost or less than full cost to people who cannot pay. If you think that you are eligible for these services, please contact our business office (give office location) and ask for assistance. If you are not satisfied with the results, you may contact (the State Hill-Burton agency with address)."

Provided, That an applicant which has selected a presumptive compliance guideline under paragraph (d)(1) of this section may, at its option, either (1) add to such notice language stating that the facility's obligation is limited to a specified dollar volume of uncompensated services and that if the facility has, during a specified period (e.g., year, quarter, month), already provided a volume of uncompensated services sufficient to satisfy such obligation, any person inquiring about such services will be given a written statement to that effect which shall also state when additional uncompensated services will be available; or (2) post an additional notice stating that the facility's obligation has been satisfied for the current period and stating when additional uncompensated services will be available.

(j) *Evaluation and enforcement.* The State plan shall provide for evaluation and enforcement of the assurance in accordance with the following requirements:

(1) The State agency shall,

(i) At least annually, perform evaluations of the amount of the various services provided in each facility with respect to which Federal assistance has been provided under the Act, to determine whether such assurance is being complied with; and

(ii) Establish procedures for the investigation of complaints that such assurance is not being complied with.

(2) Evaluation pursuant to paragraph (j)(1) of this section shall be based on the annual budget of each facility for uncompensated services and on financial statements of such facilities filed pursuant to section 646 of the Act and § 53.128(q), and on such other information, including reports of investigations and hearing decisions, as the State agency deems relevant and material.

(3) The State plan shall provide for adequate methods of enforcement of the assurance, including effective sanctions to be applied against any facility which fails to comply with such assurance. Such sanctions may include, but need not be limited to, license revocation, termination of State assistance, and court action.

(k) *Reports.* (1) The State agency shall, not less often than annually, report in writing to the Secretary its evaluation of each facility's compliance with the assurance, the disposition of each complaint received by the State agency, proposed remedial action with respect to each facility found by the State agency to be not in compliance with the assurance, and the status of such remedial action.

(2) In addition, the State agency shall promptly report to the Regional Attorney and Regional Health Director of the Department of Health and Human Services the institution of any legal action against a facility or the State agency involving compliance with the assurance.

[37 FR 14721, July 22, 1972, as amended at 38 FR 16354, June 22, 1973; 40 FR 46203, Oct. 6, 1975]

§ 53.112 Nondiscrimination.

(a) Before an application is recommended by a State agency to the Secretary for approval, the State agency shall obtain an assurance from the applicant that all portions and services of the entire facility for the construction or modernization of which, or in connection with which, aid under the Act is sought will be made available without discrimination on account of creed and no professionally qualified person will be discriminated against on account of creed with respect to the privilege of professional practice in the facility.

(b) Each construction contract is subject to the condition that the applicant shall comply with the requirements of Executive Order 11246, September 24, 1965 (30 FR 12319), relating to nondiscrimination in construction contract employment, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

(c) Attention is called to the requirement of title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d; 78 Stat. 252) which provides that no person in the United States shall, on the ground of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, applicable to assistance under this part for construction and modernization of hospitals and medical facilities, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR Part 80).

[37 FR 182, Jan. 6, 1972, as amended at 39 FR 31767, Aug. 30, 1974]

§ 53.113 Community service.

(a) *Applicability.* The provisions of this section apply to every applicant which heretofore has given or hereafter will give a community service assurance.

(b) *Definitions.* As used in this section:

(1) The term "community service assurance" means an assurance required by regulations promulgated pursuant to section 603(e)(1) of the Act or the predecessor of that section (section 622(f), Public Health Service Act, enacted by Pub. L. 79-725, 60 Stat. 1041).

(2) The term "facility" has the same meaning as is given it in § 53.111(b)(1).

(3) The term "applicant" has the same meaning as is given it in § 53.111(b)(2).

(4) The term "fiscal year" has the same meaning as is given it in § 53.111(b)(3).

(c) *Assurance.* Before an application under this part is recommended by a State agency to the Secretary for approval, the State agency shall obtain an assurance from the applicant that the facility will furnish a community service.

(d) *Compliance.* In order to comply with its community service assurance an applicant must:

(1)(i) Make the services it furnishes available to the general public, or

(ii) Limit the availability of such services only on the basis of age, medical indigency, or type or kind of medical or mental disability, or

(iii) If the facility constitutes a medical or nursing care unit of a home or other institution, make such home or other institution available in accordance with paragraph (d)(1) (i) or (ii) of this section; *and*

(2)(i) Make arrangements, if eligible to do so, for reimbursement for services with:

(A) Those principal State and local governmental third-party payors which provide reimbursement for services that is not less than the actual cost of such services as determined in accordance with accepted cost accounting principles; and

(B) Those Federal governmental third-party programs, such as Medicare and Medicaid, to the extent that the applicant is entitled to reimbursement at reasonable cost under a formula established in accordance with applicable Federal law.

(ii) Take such additional steps as may be necessary to ensure that admission to and services of the facility will be available to beneficiaries of the governmental programs specified in paragraph (d)(2)(i) of this section without discrimination (or preference) on account of their being such beneficiaries.

(e) *Reports.* The annual statement required by section 646 of the Act and § 53.128(q), a copy of which must be submitted to the State agency in accordance with the requirements of § 53.111(e)(1), shall set forth the amount of the reimbursement received pursuant to each arrangement with a principal governmental third-party payor.

(f) *Evaluation and Enforcement.* The State plan shall provide for evaluation and enforcement of the community service assurance in accordance with the following requirements:

(1) The State agency shall,

(i) At least annually, evaluate the compliance of facilities with such assurance; and

(ii) Establish procedures for the investigation of complaints that such assurance is not being complied with.

(2) The State plan shall provide for adequate methods of enforcement of the assurance, including effective sanctions to be applied against any facility which fails to comply with such assurance. Such sanctions may include, but need not be limited to, license revocation, termination of State assistance and court action.

(g) *Reports.* (1) The State agency shall, not less often than annually, report in writing to the Secretary its general evaluation of facilities' compliance with the assurance, the disposition of each complaint received by the State agency, proposed remedial action with respect to each facility found by the State agency to be not in compliance with the assurance, and the status of such remedial action.

(2) In addition, the State agency shall promptly report to the Regional Attorney and Regional Health Director of the Department of Health and Human Services the institution of any legal action against a facility or the State agency involving compliance with the assurance.

[39 FR 31767, Aug. 30, 1974, as amended at 42 FR 16780, Mar. 30, 1977]

Subpart M—Methods of Administration of the State Plan

§ 53.134 Notice of change of status of facility.

The State agency shall promptly notify the Secretary in writing if, at any time within 20 years after completion of construction, any facility which received funds under section 606 of the Act (a) is transferred to any person, agency or organization, (1) not qualified to file an application under the Act or (2) not approved as a transferee by the State agency; or (b) ceases to be a public health center or a public or other nonprofit hospital, outpatient facility, facility for long-term care or rehabilitation facility, as defined in the section 645 of the Act.

[47 FR 27860, June 28, 1982]

§ 53.135 Good cause for other use of facility.

If within 20 years after completion of any construction for which a construction grant has been made the facility shall cease to be a public health center or a public or other nonprofit hospital, outpatient facility, facility for long-term care, or rehabilitation facility the Secretary, in determining whether there is good cause for releasing the applicant or other owner of the facility from its obligation shall take into consideration the extent to which:

(a) The facility will be devoted by the applicant or other owner to use for another public or nonprofit purpose which will promote the purpose of the Act;

(b) There are reasonable assurances that for the remainder of the 20-year period other public or nonprofit facilities not previously utilized for the purpose for which the facility was constructed will be so utilized and are substantially equivalent in nature and extent for such purposes; or

(c) The facility has been acquired from an agency of the United States (e.g., the Federal Housing Administration under its mortgage insurance commitment program) which has made a reasonable effort to dispose of it for operation as a public or nonprofit facility.

Subpart N—Loan Guarantees and Direct Loans

§ 53.154 Waiver of right of recovery.

In determining whether there is good cause for waiver of any right of recovery which he may have against a nonprofit private agency by reason of any payments made pursuant to a loan guarantee, or against a public agency by reason of the failure of such agency to make payments of principal and interest on a direct loan to such agency, the Secretary shall take into consideration the extent to which:

(a) The facility with respect to which the loan guarantee or direct loan was made will continue to be devoted by the applicant or other owner to use for the purpose for which it was constructed or another public or nonprofit purpose which will promote the purposes of the Act;

(b) There are reasonable assurances that for the remainder of the repayment period of the loan other public or non-profit facilities not previously utilized for the purpose for which the facility was constructed will be so utilized and are substantially equivalent in nature and extent for such purposes; and

(c) Such recovery would seriously curtail the provision of medical services to persons in need of such services in the area.

PART 54a—GRANTS FOR ALCOHOL ABUSE AND ALCOHOLISM PREVENTION, TREATMENT, AND REHABILITATION SERVICES AND NATIONAL ALCOHOL RESEARCH CENTERS

Subparts A—D—[Reserved]

Subpart E—Grants for National Alcohol Research Centers

54a.501 Applicability.
54a.502 Definitions.
54a.503 Eligibility.
54a.504 Application.
54a.505 Program requirements.
54a.506 Grant awards.
54a.507 Expenditure of grant funds.
54a.508—54a.509 [Reserved]
54a.510 Additional conditions.

Subpart E—Grants for National Alcohol Research Centers

Authority: Sec. 504, 90 Stat. 1035 (42 U.S.C. 4588).

Source: 44 FR 17921, Mar. 28, 1979, unless otherwise noted.

§ 54a.501 Applicability.

The regulations in this subpart apply to grants to develop, establish, and support centers for interdisciplinary research relating to alcoholism and other alcohol problems, as authorized by section 504 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act (42 U.S.C. 4588).

§ 54a.502 Definitions.

Terms not defined in this section shall have the same meaning as given them in § 54a.102. As used in this subpart:

"National Alcohol Research Center" or "Center" means an institution engaged in long-term interdisciplinary research focused on a central theme relating to alcoholism and other alcohol problems.

§ 54a.503 Eligibility.

To be eligible for a grant under this subpart, an applicant must be:

(a) A public (except Federal) or nonprofit private institution which is or is affiliated with an institution (such as a university, medical center or research center) with the resources to sustain a long-term research program; and

(b) Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Trust Territory of the Pacific Islands, or the Northern Mariana Islands.

§ 54a.504 Application.

(a) Each institution desiring a grant under this subpart shall submit an application in the form and manner and on or before such dates as the Secretary may from time to time require.[1]

(b) Each private institution which does not already have on file with the National Institute on Alcohol Abuse and Alcoholism evidence of nonprofit status must submit with its application acceptable proof of its status.

(c) In addition to any other pertinent information that the Secretary may require, each application shall set forth in detail:

(1) The personnel facilities, and other resources currently available to the applicant with which to initiate and maintain the proposed Center program;

(2) Any biomedical, behavioral, or social science research related to alcohol problems in which the applicant is currently engaged; the sources of funding for those activities; and the relationship of these activities to the proposed Center program;

(3) The central theme of the proposed interdisciplinary research program;

(4) A detailed 5-year plan for the proposed Center program which identifies the principal areas of proposed research, the relationship of each area of proposed research to the central theme of the proposed Center program, the disciplines to be involved, and plans for coordination among them;

(5) A detailed description of each separate research project for which funds are requested;

(6) The names and qualifications of the Center director and key staff members who would be responsible for conducting proposed activities of the Center;

(7) The opportunities that would be available for training;

(8) The organizational structure of the proposed Center and its relationship to the organizational structure of the applicant;

(9) The proposed project period (not to exceed 5 years); a detailed budget and justification of funds requested for core support as well as for each separate research project (not exceeding $1,000,000 in total in any year); and a list of other anticipated sources of support for all research activities at the applicant institution, both planned and ongoing, relevant to alcoholism and other alcohol problems (both those to be incorporated into the proposed Center program and those outside the Center);

(10) Proposed methods for monitoring and evaluating individual research activities and the overall Center program;

(11) To the extent not covered in the information submitted under the preceding paragraphs, the manner in which the requirements in § 54a.505 will be satisfied.

[43 FR 40391, Sept. 11, 1978, as amended at 45 FR 31095, May 12, 1980]

§ 54a.505 Program requirements.

In order to receive support under this subpart, an applicant must:

(a) Have the experience or capability to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on alcoholism and other alcohol problems and to coordinate that research among such disciplines;

(b) Have available to its staff, facilities, and other resources with which to carry out the objectives of the proposed program;

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[1] Grant applications, instructions, and program guidelines may be obtained from the Director of the National Institute on Alcohol Abuse and Alcoholism, 5600 Fishers Lane, Rockville, Md. 20857.

(c) Have available to it sufficient laboratory facilities and reference services (including reference services that will afford access to scientific alcohol literature);

(d) Have facilities and personnel to provide training in the prevention and treatment of alcoholism and other alcohol problems;

(e) Have the capacity to train predoctoral and postdoctoral students for careers in research on alcoholism and other alcohol problems;

(f) Have the capacity to conduct courses on alcohol problems and research on alcohol problems for undergraduate and graduate students and for medical and osteopathic students and physicians;

(g) Provide assurances that the Center will be an identifable organizational unit of the applicant headed by a Center director resonsible for the Center program;

(h) Provide assurances that any significant changes in the Center's scientific activities or other activities will be made only with the prior approval of the Secretary; and

(i) Establish a Program Advisory Committee, chaired by the Center director, to review and make recommendations to the Center director on the conduct of all activities of the Center. The Committee shall be composed of persons who are not associated with the Center (apart from their membership on the Committee).

§ 54a.506 Grant awards.

(a) Within the limits of funds available, the Secretary, after taking into account the comments of an appropriate peer review group, may award grants to applicants with proposed programs which have been recommended for approval by the council and will in his judgment best promote the purposes of section 504 of the Act, taking into consideration among other pertinent factors:

(1) The scientific and technical merit of the proposed program and its individual components;

(2) The qualifications and experience of the Center director and other key personnel;

(3) The extent to which the various components of the proposed research program would be coordinated into an interdisciplinary effort within the Center;

(4) The administrative and managerial capability of the applicant;

(5) The reasonableness of the proposed budget in relation to the proposed program;

(6) The adequacy of proposed methods for monitoring and evaluating the overall Center program and its components including proposed mechanisms for review of the Center's program by its Program Advisory Committee;

(7) The potential of the proposed Center to become a significant regional and national research resource; and

(8) The degree to which the application adequately provides for the requirements of § 54a.505.

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 5 years.

(c) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of those awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In any case, a grant award shall not exceed $1 million in any fiscal year. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(e) An initial 5-year project period may be extended by the Secretary for additional periods not in excess of 5 years each, after review of the operations of the grantee by an appropriate peer review group and with the Council's recommendation for approval, except that if an additional period of support involves only the expenditure of funds previously awarded, peer review and consultation with the Council are not required.

[43 FR 40391, Sept. 11, 1978, as amended at 45 FR 31095, May 12, 1980]

§ 54a.507 Expenditure of grant funds.

(a) Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations on this part, the terms and conditions of the award, and the applicable cost principles prescribed by Subpart Q of 45 CFR part 74, except that those funds may not be expended for trainee stipends, fees, or other expenses directly relating to training or for the purchase or rental of any land or the rental, purchase, construction, preservation, or repair of any building. For purposes of this paragraph, construction means the construction of new buildings, and the expansion, remodeling, and alteration of existing buildings, including architects' fees, but not including the cost of acquisition of land or off-site improvements, and equipping new buildings and existing buildings, whether or not expanded, remodeled, or altered.[3]

(b) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess.

[43 FR 40391, Sept. 11, 1978, as amended at 45 FR 31095, May 12, 1980]

§§ 54a.508—54a.509 [Reserved]

§ 54a.510 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment those conditions are necessary to assure or protect advancement of the approved program, the interest of public health or the conservation of grant funds.

PART 55a—PROGRAM GRANTS FOR BLACK LUNG CLINICS

Sec.

55a.1 To whom do these regulations apply?
55a.2 Definitions.
55a.3 Who is eligible to apply for a Black Lung Clinics grant?
55a.4 What must an application for a Black Lung Clinics grant contain?
55a.5 What requirements must a Black Lung Clinic meet?
55a.6 What criteria has HHS established for deciding which grant applications to fund?
55a.7 How may project funds be used?
55a.8 What other HHS regulations apply?
55a.9 What confidentiality requirements must be met?

AUTHORITY: Sec. 508, 83 Stat. 803; 30 U.S.C. 937.

SOURCE: 45 FR 72161, Oct. 31, 1980, unless otherwise noted.

§ 55a.1 To whom do these regulations apply?

This part applies to the award of grants pursuant to section 427(a) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 937(a)). These grants support the operation of clinical facilities known as Black Lung Clinics, for analysis, examination and treatment of respiratory and pulmonary impairments in coal miners.

§ 55a.2 Definitions.

Any term not defined here shall have the meaning given it in the Act. As used in this part:

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[3] Section 504(b) of the Act provides that for the purposes of that paragraph the term "construction" shall have the meaning given to it by section 702(2) of the Public Health Service Act (42 U.S.C. 292a). The above definition incorporates the language of section 702(2) in effect on July 26, 1976, the date of the enactment of section 504 by Pub. L. 94-371.

"Act" means the Federal Mine Safety and Health Act of 1977, as amended (30 U.S.C. 801 et seq.).

"Applicant" means any public or nonprofit private agency or institution which files an application for a grant under this part.

"Miner" or "coal miner" means any individual who works or has worked in or around a coal mine or coal preparation facility in the extraction or preparation of coal. The term also includes an individual who works or has worked in coal mine construction or transportation in or around a coal mine, to the extent that the individual was exposed to coal dust as a result of employment.

"Nonprofit," as applied to an agency or institution, means that no part of the net earnings of such agency or institution benefits, or may lawfully benefit, any private shareholder or individual.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

§ 55a.3 Who is eligible to apply for a Black Lung Clinics grant?

(a) Any public or private nonprofit entity may apply for a grant under this part.

(b) Eligible projects: grants pursuant to section 427(a) of the Act and this part may be made to eligible applicants for carrying out area or statewide clinical services for the analysis, examination, and treatment of occupational respiratory and pulmonary impairments in coal miners.

§ 55a.4 What must an application for a Black Lung Clinics grant contain?

An approvable application must contain each of the following:

(a) A plan for the provision of the services required by this part containing at least the following elements:

(1) A description of the target population to whom services are to be provided, including a statement of the need for services;

(2) A description of the area in which the target population resides, including descriptions of geographical barriers to service, availability of transportation, and each of the health service providers in the area which provide any of the services required under this part;

(3) A statement of the goals and objectives of the program, how the program intends to achieve them, and how progress toward their achievement will be measured;

(4) A description of how existing resources in the community will be utilized to maximize the effectiveness and efficiency of the use of grant funds; and

(5) Letters of intent from each entity which is expected to provide any service under the Black Lung Clinics Program, including a statement that, contingent upon a grant award, services will be provided in accordance with the requirements under this part.

(b) An assurance that, should an award be made, the grantee will enter into binding agreements with each of the listed clinics providing letters of intent which shall include provisions that:

(1) No person will be denied services because of inability to pay;

(2) Services will be made available regardless of how long the miner has lived in the service area or whether anyone referred the miner to the clinic;

(3) Services will be made available in a manner calculated to preserve human dignity and to maximize acceptability and utilization of services;

(4) Charges shall be made for services rendered as follows:

(i) A schedule shall be maintained listing fees or payments for the provision of services, designed to cover reasonable costs of operation;

(ii) A schedule of discounts adjusted on the basis of a patient's ability to pay shall be maintained. The schedule of discounts must provide for a full discount to individuals and families with annual incomes at or below the levels set forth in the most recent Community Services Administration *Income Poverty Guidelines* at 42 CFR 1060.2 (except that nominal fees for service may be collected from individuals and families with annual incomes at or below those levels if imposition of the fees is consistent with project goals). No discounts shall be provided to individuals and families with annual incomes greater than twice those set forth in the Guidelines;

(iii) Where third-party payors (including Government agencies) are authorized or under a legal obligation to pay all or a portion of such charges, all services covered by that reimbursement plan will be billed and every reasonable effort will be made to obtain payment; and

(iv) Where the cost of care and services furnished under the program is to be reimbursed under Title XIX of the Social Security Act, a written agreement with the Title XIX agency will be obtained by the clinic unless the Title XIX agency refuses to enter into the agreement and the clinic provides evidence of the refusal to the grantee.

(5) Grant funds will be used to supplement and not supplant existing services.

(6) Medical services will be performed in consultation with a physician with special training or experience in the diagnosis and treatment of respiratory diseases.

(c) A description of how each clinic or group of clinics will assure consumer participation in the development of policy applicable to the administration and delivery of black lung clinic services through a policy board or an advisory committee to the policy board. If the policy board consists of a majority of miners or miner-selected representatives, this requirement is satisfied. If this is not the case, an advisory committee to the policy board with a majority of miners or miner-selected representatives, but also including interested parties, such as health care providers, coal industry employers, representatives of third-party payors, and the general public, must be established. Procedures for the functioning of the advisory committee must be adopted which assure continued ability to represent the varied points of view, including that of consumers, and that committee recommendations are promptly referred to the policy board for consideration.

(d) Evidence that a copy of the application was forwarded to each of the affected health systems agencies designated under Title XV of the Public Health Service Act with a request that the agency review and approve the application and forward its comments to the Secretary. Regulations applying to health systems agencies appear in 42 CFR Part 122.

(e) Evidence that the application was sent to the appropriate A-95 Clearinghouse(s) for review and comment, in compliance with Office of Management and Budget Circular No. A-95, Revised.

§ 55a.5 What requirements must a Black Lung Clinic meet?

For inclusion in an applicant's plan, clinics must now, or with grant assistance be able to:

(a) Provide for the following services:

(1) Primary care;

(2) Patient and family education and counseling;

(3) Outreach;

(4) Patient care coordination, including individual patient care plans for all patients;

(5) Antismoking advice; and

(6) Other symptomatic treatments.

(b) Meet all criteria for approval and designation by the Department of Labor under 20 CFR Part 725 to perform disability examinations and provide treatment under the Act.

§ 55a.6 What criteria has HHS established for deciding which grant applications to fund?

(a) Within the limits of funds available for these purposes, the Secretary may award grants to assist in the carrying out of those programs which will in the Secretary's judgment best promote the purposes of section 427(a) of the Act, taking into account:

(1) The number of miners to be served and their needs;

(2) The quality and breadth of services to be provided;

(3) The degree to which other resources are committed to the program;

(4) The applicant's ability to manage the proposed program, including its experience with the delivery of medical services by clinical facilities and its ability to make rapid and effective use of the grant funds; and

(5) Whether proposed services are complementary to and nonduplicative of existing services, particularly in States or Regions where there are existing programs which are determined to be meeting or making satisfactory progress toward meeting identified needs.

(b) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3 to 5 years.

(c) Generally the grant initially will be for 1 year and subsequent continuation awards also will be for 1 year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 55a.7 How may project funds be used?

A grantee shall only spend funds it receives under this part according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and the regulations of this part.

§ 55a.8 What other HHS regulations apply?

Several other HHS regulations apply to grants under this part. These include, but are not limited to:

42 CFR Part 50—Policies of general applicability

42 CFR Part 122—Health systems agency reviews of certain proposed uses of Federal health funds

45 CFR Part 16—Department grant appeals process

45 CFR Part 19—Limitation on payments or reimbursements for drugs

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health, Education, and Welfare—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedures for hearings under Part 80 of this title

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 91[1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance

§ 55a.9 What confidentiality requirements must be met?

All information as to personal facts and circumstances obtained by the grantee's staff about recipients of services shall be held confidential, and shall not be disclosed without the individual's consent except as may be required by law or as may be necessary to provide service to the individual or to provide for medical audits by the Secretary with appropriate safeguards for confidentiality of patient records. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

PART 56—GRANTS FOR MIGRANT HEALTH SERVICES

Subpart A—General Provisions

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56.104 Application.
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56.107 Priorities for grants.
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Subpart G—Grants for Technical Assistance

56.701 Applicability.
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Subpart H—Acquisition and Modernization of Existing Buildings

56.801 Applicability of 42 CFR Part 51c, Subpart E.

AUTHORITY: Secs. 215, 319, Public Health Service Act (42 U.S.C. 216, 247d).

SOURCE: 42 FR 60406, Nov. 25, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 56.101 Applicability.

The regulations of this subpart are applicable to all grants authorized by Section 319 of the Public Health Service Act (42 U.S.C. 247d).

§ 56.102 Definitions.

As used in this part:

(a) "Act" means the Public Health Service Act (42 U.S.C. 201 *et seq.*), as amended.

(b)(1) "Agriculture" means farming in all its branches, including—

(i) Cultivation and tillage of the soil;

(ii) The production, cultivation, growing, and harvesting of any commodity grown on, in, or as an adjunct to or part of a commodity grown in, or on, the land; and

(iii) Any practice (including preparation and processing for market and delivery to storage or to market or to carriers for transportation to market) performed by a farmer or on a farm incident to or in conjunction with an activity described in subsection (ii).

(c) "Catchment area" means the geographic area served by a project funded under section 319 of the Act.

(d) "Environmental health services" means the detection and alleviation of unhealthful conditions of the environment of the persons served by the project, such as problems associated with water supply, sewage treatment, solid waste disposal, rodent and parasite infestation, field sanitation, and housing conditions and the treatment of medical conditions arising therefrom. For the purposes of this part, the detection and alleviation of unhealthful conditions of the environment includes the notification of appropriate Federal, State, or local authorities responsible for correcting such conditions and the making of arrangements therefor with such authorities.

(e) "Health professionals" means professionals (such as physicians, dentists, nurses, podiatrists, optometrists, and physicians' extenders) who are engaged in the delivery of health services and who meet all applicable Fed-

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eral or State requirements to provide their professional services.

(f) "High impact area" means a catchment area which has not less than 6,000 migratory agricultural workers, seasonal agricultural workers, and members of the families of such workers residing within its boundaries for more than two months in the most recent calendar year for which statistical data acceptable to the Secretary is available.

(g)(1) "Migrant health center" means an entity which either through its staff and supporting resources or through contracts or cooperative arrangements with other public or private entities provides for migratory agricultural workers, seasonal agricultural workers, and the members of the families of such workers, within its catchment area:

(i) Primary health services;

(ii) As determined by the Secretary to be appropriate for particular centers, supplemental health services necessary for the adequate support of primary health services;

(iii) Referral to providers of supplemental health services and payment, as determined by the Secretary to be appropriate and feasible, for the provision of such services;

(iv) Environmental health services, as determined by the Secretary to be appropriate for particular centers;

(v) As determined by the Secretary to be appropriate for particular centers, infectious and parasitic disease screening and control services;

(vi) As determined by the Secretary to be appropriate for particular centers, accident prevention programs, including prevention of excessive exposure to pesticides through, but not limited to, notification of appropriate Federal, State or local authorities of hazardous conditions due to pesticide use; and

(vii) Information on the availability and proper use of health services.

(2) For purposes of paragraph (g)(1) of this section, the provision of a given service by a center will be determined by the Secretary to be appropriate where

(i) There is a need, as determined by the Secretary, for the provision of such service to individuals described in paragraph (g)(1) of this section in the catchment area; and

(ii) The provision of such service by the center is feasible, taking into consideration the center's projected revenues, other resources, and grant support under this part.

(h) "Migratory agricultural worker" means an individual whose principal employment is in agriculture on a seasonal basis, who has been so employed within the last 24 months, and who establishes for the purpose of such employment a temporary place of abode;

(i) "Nonprofit", as applied to any private agency, institution, or organization, means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(j) "Physician" means a licensed doctor of medicine or doctor of osteopathy.

(k) "Primary care" means preventive, diagnostic, treatment, consultant, referral, and other services rendered by physicians (including, as appropriate, physicians' extenders), routine associated laboratory services and diagnostic radiologic services, and emergency health services.

(l) "Primary health services" means:

(1) Diagnostic, treatment, consultative referral, and other services rendered by physicians and, where feasible, by physicians' extenders, such as physicians' assistants, nurse clinicians, and nurse practitioners;

(2) Diagnostic laboratory services and diagnostic radiologic services;

(3) Preventive health services, including children's eye and ear examinations, prenatal and post-partum care, perinatal services, well child care (including periodic screening), immunizations, and voluntary family planning services;

(4) Emergency medical services, including provision, through clearly defined arrangements, for access of users of the center to health care for medical and dental emergencies during and after the center's regularly scheduled hours;

(5) Transportation services as needed for adequate patient care, suf-

ficient so that residents of the catchment area served by the center with special difficulties of access to services provided by the center receive such services; and

(6) Preventive dental services provided by a licensed dentist or other qualified personnel, including—

(i) Oral hygiene instruction;

(ii) Oral prophylaxis, as necessary; and

(iii) Topical application of fluorides, and the prescription of fluorides for systemic use when not available in the community water supply.

(m) "Seasonal agricultural worker" means an individual whose principal employment is in agriculture on a seasonal basis and who is not a migratory agricultural worker.

(n) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(o) "Supplemental health services" means health services which are not included as primary health services and which are:

(1) Inpatient and outpatient hospital services;

(2) Home health services;

(3) Extended care facility services;

(4) Rehabilitative services (including physical and occupational therapy) and long-term physical medicine;

(5) Mental health services, including services of psychiatrists, psychologists, and other appropriate mental health professionals;

(6) Dental services other than those provided as primary health services;

(7) Vision services, including routine eye and vision examinations and provision of eyeglasses, as appropriate and feasible;

(8) Allied health services;

(9) Pharmaceutical services, including the provision of prescription drugs;

(10) Therapeutic radiologic services;

(11) Ambulatory surgical services;

(12) Public health services (including nutrition education and social services);

(13) Health education services; and

(14) Services including the services of outreach workers, which promote and facilitate optimal use of primary health services and services referred to in the preceding subparagraphs of this paragraph and, if a substantial number of individuals in the population served by the center are of limited English-speaking ability, the services of outreach workers and other personnel fluent in the language or languages spoken by such individuals.

§ 56.103 Eligibility.

Any public or nonprofit private entity is eligible to apply for a grant under this part.

§ 56.104 Application.

(a) An application for a grant under this part shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.

(b) The application shall contain a budget and narrative plan of the manner in which the applicant intends to conduct the project and carry out the requirements of this part. The application must describe how and the extent to which the project has met, or plans to meet, each of the requirements in Subpart B (relating to grants for planning and development of migrant health centers), Subpart C (relating to grants for the operation of migrant health centers), Subpart D (relating to grants for the operation of migrant health entities), Subpart E (relating to grants for planning and developing migrant health programs), Subpart F (relating to grants for the operation of migrant health programs), or Subpart G (relating to grants for technical assistance), as applicable. In addition, applications must include:

(1) A statement of specific, measurable objectives and the methods to be used to assess the achievement of the objectives in specified time periods and at least on an annual basis.

(2) The precise boundaries of the catchment area to be served by the applicant. In addition, the application shall include information sufficient to enable the Secretary to determine that the applicant's catchment area meets the following criteria:

(i) The size of such area is such that the services to be provided by the applicant are available and accessible to the residents of the area promptly and as appropriate;

(ii) The boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and areas served by Federal and State health and social service programs; and

(iii) The boundaries of such area eliminate, to the extent possible, barriers resulting from the area's physical characteristics, its residential patterns, its economic and social groupings, and available transportation.

(3)(i) The number of migratory agricultural workers and members of their families, and seasonal agricultural workers and members of their families which resided in the project's catchment area in the most recent calendar year for which statistical data acceptable to the Secretary is available; and

(ii) The approximate period or periods of residence of all groups of migratory agricultural workers and their families counted under paragraph (b)(3)(i) of this section.

(4) The results of an assessment of the need that the population to be served has for the services to be provided by the project (or in the case of applications for planning and development projects, the methods to be used in assessing such need), taking into consideration the following factors:

(i) Available health resources in relation to size of the catchment area and population of migratory and seasonal agricultural workers and their families in such area, including appropriate ratios of primary care physicians in general or family practice, internal medicine, pediatrics, or obstetrics and gynecology, to such population;

(ii) Health indices for such population, such as infant mortality rate;

(iii) Economic factors affecting such population's use of health services, such as percentage of such population with incomes below the poverty level;

(iv) Demographic factors affecting such population's need and demand for health services, such as percentage of such population age 65 and over; and

(v) Special factors of access resulting from the conditions of employment of such workers (including working hours, housing, and sanitation).

(5) Position descriptions for personnel who will be utilized in carrying out the activities of the project and a statement indicating the need for the positions to be supported with grant funds to accomplish the objectives of the project.

(6) Letters and other forms of evidence showing that efforts have been made to secure financial and professional assistance and support for the project within the proposed catchment area and the continuing involvement of the community in the development and operation of the project.

(7) An assurance that an independent certified public accountant will be engaged to certify that the project's system for the management and control of its finances will be in accord with sound financial management practices, including applicable Federal requirements.

(8) A list of all services proposed to be provided by the project.

(9) A list of services which are to be provided directly by the project through its own staff and resources and a description of any contractual or other arrangements (including copies of documents, where available) entered into, or planned for the provision of services.

(10) The schedule of fees and/or payments and schedule of discounts for services provided by the project.

(11) If the applicant provides services to populations other than migratory and seasonal agricultural workers and their families, identification of such populations.

NOTE.—Funds granted under this part and non-Federal funds required to be expended by the project as a condition of any such grant may not be used to provide services to individuals who are not migratory or seasonal agricultural workers or members of the families of such workers.

(12) Evidence that:

(i) The requirements of Part I of Office of Management and Budget Circular No. A-95 have been satisfied; and

(ii) All applicable requirements for review and/or approval of the application under Title XV of the Act have been met.

(13) An assurance that the project will be conducted in accordance with the applicable requirements of this part.

(c) The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the applicable regulations of this part, and any additional conditions of the grant.

§ 56.105 Accord with health planning.

A grant may be made under this part only if the applicable requirements of Title XV of the Act relating to review and approval by the appropriate health planning agencies have been met.

§ 56.106 Amount of grant.

(a) The amount of any award under this part will be determined by the Secretary on the basis of his estimate of the sum necessary for a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary: *Provided, however,* That no grant shall be made for an amount in excess of the total costs found necessary by the Secretary to carry out the project.

(i) In determining the percentage of project costs to be borne by the grantee, factors which the Secretary will take into consideration will include the following:

(A) The ability of the grantee to finance its share of project costs from non-Federal sources;

(B) The need in the area served by the project for the services to be provided; and

(C) The extent to which the project will provide services in an innovative manner which the Secretary desires to stimulate in the interest of developing more effective health service delivery systems on a regional or national basis.

(ii) At any time after approval of an application under this part, the Secretary may retroactively agree to a percentage of project costs to be borne by the grantee lower than that determined pursuant to paragraph (a)(2)(i) of this section where he finds that changed circumstances justify a smaller contribution.

(iii) In determining the grantee's share of project costs, costs borne by Federal grant funds, or costs used to match other Federal grants, may not be included except as otherwise provided by law or regulations.

(b) All grant awards shall be in writing, and shall set forth the amount of funds granted and the period for which support is recommended.

(c) Neither the approval of any project nor any grant award, shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application.

§ 56.107 Priorities for grants.

(a) Grants under sections 319(c)(1)(A), 319(d)(1)(A), 319(d)(1)(B) of the Act and Subparts B, C, and D of this part shall be made in accordance with the following priorities:

(1) Highest priority will be given to approvable applications which propose to serve catchment areas in which 6,000 or more migratory agricultural workers and members of their families reside for more than two months in the calendar year.

(2) Second priority will be given to approvable applications which propose to serve catchment areas in which

fewer than 6,000 but more than 1,000 migratory agricultural workers and members of their families reside for more than two months in the applicable calendar year.

(3) Third priority will be given to approvable applications which propose to serve catchment areas in which migratory agricultural workers and members of their families reside but in which fewer than 1,000 such persons reside for more than two months in the applicable calendar year.

(4) Fourth priority will be given to approvable applications which propose to serve catchment areas in which migratory agricultural workers and members of their families reside in the applicable calendar year but in which no such persons reside for more than two months in such year.

(5) Fifth priority will be given to approvable applications which propose to serve catchment areas in which no migratory agricultural workers or members of their families reside for any period in the applicable calendar year but in which 6,000 or more seasonal agricultural workers and the members of their families reside.

(6) Lowest priority will be given to approvable applications which propose to serve catchment areas in which no migratory agricultural workers or members of their families reside for any period in the applicable calendar year and in which fewer than 6,000 seasonal agricultural workers and the members of their families reside.

(b) Grants under sections 319(c)(1)(B) and 319(d)(1)(C) of the Act and Subparts E and F of this part will be made in accordance with priorities set forth in paragraphs (a)(2) through (a)(6) of this section, in the order set forth.

(c) For the purposes of this section, the applicable calendar year will be the calendar year for which data is provided in accordance with § 56.104(b)(3) of this subpart.

§ 56.108 Use of grant funds.

(a) Any funds granted pursuant to this part, as well as other funds to be used in performance of the approved project, may be expended solely for carrying out the approved project in accordance with section 319 of the Act, the applicable regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

(b) Project funds awarded under this part may be used for, but need not be limited to, the following:

(1) The costs of acquiring and modernizing existing buildings (including the costs of amortizing the principal of, and paying interest on, loans), but only in accordance with Subpart H of this part and as approved in the grant award;

(2) The costs of obtaining technical assistance to develop and improve the management or service capability of the project but only as approved by the Secretary;

(3) To reimburse members of the grantee's governing board established pursuant to § 56.304 of Subpart C, or advisory council established pursuant to § 56.603(q) of Subpart F, if any, for reasonable expenses actually incurred by reason of their participation in the activities of such board or council;

(4) To reimburse such governing board or advisory council members who are individuals eligible to be served by the project for wages lost by reason of participation in the activities of such board or council;

(5) The cost of delivering health services to migratory agricultural workers, seasonal agricultural workers and the members of their families within the project's catchment area, within the following limitations: grant funds may be used to pay the full cost of project services to such individuals and families with annual incomes at or below those set forth in the most recent "CSA Income Poverty Guidelines" (45 CFR 1060.2) issued by the Community Services Administration, and to pay the portion of the cost of services provided in accordance with the schedule of discounts which, under such schedule, is uncompensated; *Provided*, That

(i) Charges will be made to such individuals and families in accordance with § 56.303(f) of Subpart C or § 56.603(e) of Subpart F, as applicable;

(ii) Reasonable effort shall be made to collect such charges under a billing and collections system; and

(iii) The charge to grant funds shall exclude any amounts collected pursuant to paragraph (b)(5)(ii) of this section;

(6) The cost of insurance for medical emergency and out-of-area coverage; and

(7) The cost of providing to the staff and governing board, if any, of the project training related to the management of an ambulatory care facility, and to the staff of a project funded under Subpart C, D, or F of this part, training related to the provision of primary, supplemental and environmental health services provided or to be provided by the project, consistent with the applicable requirements of 45 CFR Part 74.

(c) Prior approval by the Secretary of revisions of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

§ 56.109 Grant payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred, to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 56.110 Nondiscrimination.

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d *et seq.*) and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR Part 80). In addition, no person shall, on the grounds of age, sex, creed, or marital status (unless otherwise medically indicated), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity so receiving Federal financial assistance.

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

§ 56.111 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about recipients of services shall be held confidential and shall not be divulged without the individual's consent except as may be required by law or as may be necessary to provide service to the individual or to provide for medical audits by the Secretary or his designee with appropriate safeguards for confidentiality of patient records. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 56.112 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 56.113 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project, the grantee shall account for the sum total of all amounts paid as well as other funds and in-kind contributions by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for interest earned on grant funds.* Pursuant to Section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the government of the political subdivisions of the State. All grantees other than a State, as so defined, must return all interest earned on grant funds to the Federal Government.

(c) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project, the sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (b) of this section;

(iii) Any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

§ 56.114 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part to States and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to all other grantee organizations under this part:

45 CFR PART 74

Subpart	
A	General.
B	Cash depositories.
C	Bonding and insurance.
D	Retention and custodial requirements for records.
F	Grant-related income.
G	Matching and cost sharing.
K	Grant payment requirements.
L	Budget revision procedures.
M	Grant closeout, suspension, and termination.
O	Property.
Q	Cost principles.

Subpart B—Grants for Planning and Developing Migrant Health Centers

§ 56.201 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A of this part, are applicable to grants awarded pursuant to section 319(c)(1)(A) of the Act for projects for planning and developing migrant health centers in high impact areas.

§ 56.202 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 56.104 of Subpart A of this part, contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of this part.

§ 56.203 Project elements.

A project for planning and developing a migrant health center supported under this subpart must:

(a) Determine (by survey or other appropriate means) the approximate number of (1) migratory agricultural workers and the members of their families, and (2) seasonal agricultural workers and the members of their families, within the proposed catchment area in the calendar year in which the grant is made and the period of time these workers and their families reside in the catchment area during such year.

(b) Prepare an assessment of the need of the population proposed to be served by the migrant health center for the services set forth in § 56.102(g)(1) of Subpart A of this part. This assessment of need must, at a minimum, include the factors listed in § 56.104(b)(3) (i)-(iv).

(c) Design a migrant health center program for such population, based on the assessment prepared pursuant to paragraph (b) of this section which indicates in detail how the proposed center will fulfill the needs identified in that assessment and meet the requirements of Subpart C of this part.

(d) Develop a plan for the implementation of the program designed pursuant to paragraph (c) of this section. This implementation plan must provide for the time-phased recruitment and training of the personnel essential for the operation of a migrant health center and the gradual assumption of operational status of the project so that the project will, in the judgment of the Secretary, meet the requirements contained in Subpart C of this part by the end of the project period.

(e) Implement the plan developed pursuant to paragraph (d) of this section in accordance with such paragraph.

(f) Make efforts to secure within the proposed catchment area of such center, to the extent possible, financial and professional assistance and support for the project.

(g) Initiate and encourage continuing community involvement in the development and operation of the project through, for example, contributions or loans of cash, services, equipment, full-or part-time staff, space, materials, or facilities.

(h) Provide for sufficient staff, qualified by training and experience, to carry out the project and establish standards and qualifications for personnel (including the project director).

(i) Utilize, to the maximum extent feasible, other Federal, State, local, and private resources available for support of the project, prior to use of project funds under this subpart.

(j) Provide the means for evaluating the project's progress in achievement of its specific objectives, and submit such progress reports on the project as the Secretary may from time to time request.

§ 56.204 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which, in his judgment, will provide needed health services in a catchment area which will not be served by another project funded under this part and meet the applicable requirements of section 319(c)(1)(A) of the Act and this part, in accordance with priorities established pursuant to section 319(b) of the Act and § 56.107 of Subpart A of this part; *Provided*, That in the case of applicants which propose to serve substantially the same catchment areas or where available funds are insufficient to fund all approvable applications within a priority category specified in § 56.107,

(1) Priority shall be given to applications submitted by community-based organizations which are representative of the population to be served by the project. For purposes of this paragraph, an applicant shall be deemed to be such an organization if it provides a formal mechanism (such as membership on the organization's governing body or membership on an advisory body) which gives migratory seasonal agricultural workers and their families significant involvement in the formulation of the organization's policies; and

(2) Where all such applicants are community-based organizations representative of the population to be served by the project, the Secretary shall award the grant to the applicants which will, in his judgment, best

promote the purposes of section 319(c)(1)(A) of the Act and the applicable regulations of this part, taking into account with respect to each application:

(i) The degree to which the proposed project satisfactorily provides for the elements set forth in § 56.203;

(ii) The administrative and management capability of the applicant;

(iii) The extent to which community resources will be utilized in the project; and

(iv) The degree to which the applicant intends to integrate services supported by a grant under this part with health services provided under other federally assisted health services or reimbursement programs or projects.

(b) The Secretary shall award no more than two grants under this subpart for the same project.

Subpart C—Grants for Operating Migrant Health Centers

§ 56.301 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A of this part, are applicable to grants awarded pursuant to section 319(d)(1)(A) of the Act for the costs of operation of migrant health centers in high impact areas.

§ 56.302 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 56.104 of Subpart A of this part,

(a) Be submitted by an entity (which may be a co-applicant) which the Secretary determines is a migrant health center, and

(b) Contain information sufficient to enable the Secretary to determine that the center will meet the requirements of this part.

§ 56.303 Project elements.

A migrant health center supported under this subpart must:

(a) Provide the health services of the center so that such services are available and accessible promptly, as appropriate, and in a manner which will assure continuity of service to the migratory and seasonal agricultural workers and their families within the center's catchment area.

(b) Implement a system for maintaining the confidentiality of patient records in accordance with the requirements of § 56.111 of Subpart A of this part.

(c) Have an ongoing quality assurance program which provides for the following:

(1) Organizational arrangements, including a focus of responsibility, to support the quality assurance program and the provision of high quality patient care;

(2) Periodic assessment of the appropriateness of the utilization of services and the quality of services provided or proposed to be provided by the center, and by other providers through contract or other cooperative arrangement with the center. Such assessments must:

(i) Be conducted by physicians or by other appropriate health professionals under the supervision of physicians or, as appropriate, by health professionals who are peers of the health professionals who provided the services;

(ii) Be based on the systematic collection and evaluation of patient records; and

(iii) Identify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated.

(d) Develop management and control systems which are in accordance with sound financial management procedures, including the provision for an audit (1) conducted in accordance with the "Guide for Audits of Migrant Health Grants" of the DHHS Audit Agency, and (2) conducted with reasonable frequency, usually annually but not less frequently than every two years (unless waived for cause by the Secretary), to be made by qualified individuals who are sufficiently independent of those who authorize the expenditure of Federal funds to produce unbiased opinions, conclusions, or judgments, and to determine, at a minimum, the fiscal integrity of grant financial transactions and reports, and compliance with the applicable regulations of this part and the terms and conditions of the grant.

(e) Where the cost of care and services furnished by or through the center is to be reimbursed under Title XIX or Title XX of the Social Security Act, obtain or make every reasonable effort to obtain a written agreement with the Title XIX or Title XX State agency for such reimbursement.

(f) Have prepared a schedule of fees or payments for the provision of its services designed to cover its reasonable costs of operation and a corresponding schedule of discounts adjusted on the basis of the patient's ability to pay. The schedule of discounts must provide for a full discount to individuals and families with annual incomes at or below those set forth in the most recent CSA Poverty Income Guidelines (42 CFR 1060.2) (except that nominal fees for service may be collected from such individuals and families) and for no discount to individuals and families with annual incomes greater than twice those set forth in such Guidelines.

(g) Make every reasonable effort, including the establishment of systems for eligibility determination, billing, and collection, to

(1) Collect reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under Title XVIII of the Social Security Act, to medical assistance under a State plan approved under Title XIX of such Act, to social services and family planning under Title XX of such Act, or to assistance for medical expenses under any other public assistance program, grant program, or private health insurance or benefit program on the basis of the schedule of fees prepared pursuant to paragraph (f) of this section without application of any discounts, and

(2) Secure from patients payments for services in accordance with the schedule of fees and discounts required by paragraph (f) of this section.

(h) Have a governing board which meets the requirements of § 56.304.

(i) Have developed an overall plan and budget for the center that:

(1) Provides for an annual operating budget and a three-year financial management plan which includes all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items;

(2) Provides for a capital expenditure plan for at least a three-year period (including the year to which the operating budget described in paragraph (h)(i)(1) is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objective of, each anticipated expenditure in excess of $100,000 related to the acquisition of land, the improvement of land, buildings, and equipment and the replacement, modernization and expansion of buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(3) Provides for plan review and updating at least annually; and

(4) Is prepared under the direction of the governing board by a committee consisting of representatives of the governing board, the administrative staff, and the medical staff, if any, of the center.

(j) Establish basic statistical data, cost accounting, management information, and reporting or monitoring systems which will enable the center to provide such statistics and other information as the Secretary may reasonably require relating to the center's costs of operation, patterns of utilization of services, and the availability, accessibility, and acceptability of its services, and to make such reports to the Secretary in a timely manner with such frequency as the Secretary may reasonably require.

(k) Review its catchment area annually to insure that the criteria set out in § 56.104(b)(2) are met and, if criteria are not met, revise its catchment area, with the approval of the Secretary, to conform with such criteria to the extent feasible.

(l) In the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, have developed a plan and made arrangements responsive to the needs of such populations for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and have identified an individual on its staff who is fluent in both that language and in English and whose responsibilities include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences. If more than one non-English language is spoken by such group or groups, an individual or individuals fluent in those languages and English must be so identified.

(m) Be operated in a manner calculated to preserve human dignity and to maximize acceptability and effective utilization of services.

(n) To the extent possible, coordinate and integrate project activities with the activities of other federally funded, as well as State and local, health services delivery projects and programs serving the same population.

(o) Establish means for evaluating progress toward the achievement of the specific objectives of the project.

(p) Provide sufficient staff, qualified by training and experience, to carry out the activities of the center.

(q) Assure that facilities utilized in the performance of the project meet applicable fire and life safety codes.

(r) Utilize, to the maximum extent feasible, other Federal, State and local, and private resources available for support of the project, prior to use of project funds under this part.

(s) Provide for community participation through, for example, contributions of cash or services, loans of full- or part-time staff, equipment, space, materials, or facilities.

(t) Where the center will provide services through contract or other cooperative arrangements with other providers of services, the center must:

(1) Enter into the contract or arrangement only if the provider of services will provide the services in a timely manner and make the services accessible and acceptable to the population to be served;

(2) Make payment for services so provided only pursuant to agreements with the providers in accordance with a schedule of rates and payment procedures established and maintained by the center. The center must be prepared to substantiate that such rates are reasonable and necessary;

(3) Directly provide at least primary care unless the center has made arrangements for the provision of primary care which include transfer of all medical and financial information relating to such care to the center; and

(4) Enter into contracts or arrangements for the provision of primary health services only if alternative resources are reasonably available to provide these services in the event of termination of such arrangements.

(u) Operate in a manner such that no migratory or seasonal agricultural worker or member of their family will be denied service by reason of his or her inability to pay therefor. *Provided, however,* That a charge for the provision of services will be made to the extent that a third party (including a Government agency) is authorized or is under legal obligation to pay such charges.

§ 56.304 Governing board.

The governing board of the center must meet the following requirements:

(a) *Size.* The board must consist of at least 9 but not more than 25 members except that this provision may be waived by the Secretary for good cause shown.

(b) *Composition.* (1) A majority of the board members must be migratory and seasonal agricultural workers and members of their families who are or will be served by the center and who, as a group, represent the individuals being or to be served in terms of demographic factors, such as race, ethnicity, and sex.

(2) No more than two-thirds of the remaining members of the board may be individuals who derive more than 10 percent of their annual income from the health care industry.

(3) The remaining members of the board must be representatives of the community in which the center's catchment area is located and shall be selected for their expertise in relevant subject areas, such as community affairs, local government, finance and banking, legal affairs, trade unions, and other commercial and industrial concerns, or social services within the community.

(4) No member of the board shall be an employee of the center, or spouse or child, parent, brother or sister by blood of marriage of such an employee. The project director may be a non-voting, ex-officio member of the board.

(c) *Selection of members.* The method of selection must be prescribed in the by-laws or other internal governing rules of the center. Such by-laws or other rules must specify a process of selection of individuals on the governing board who represent the population served or to be served by the center so that such individuals, as a group, are representative of such population. Such process of selection in the by-laws or other rules is subject to approval by the Secretary.

(d) *Functions and responsibilities.* (1) The governing board shall have authority for the establishment of policy in the conduct of the center.

(2) The governing board shall hold regularly scheduled meetings, at least once each month, except for periods of the year, as specified in the bylaws, during which monthly meetings are not practical due to migration out of the catchment area.

(3) Minutes must be kept for all regularly scheduled meetings of the board.

(4) The governing board shall have specific responsibility for:

(i) Approval of the selection and dismissal of the project director or chief executive officer of the center;

(ii) Establishing personnel policies and procedures, including selection and dismissal procedures, salary and benefit scales;

(iii) The development of bylaws which specify the responsibility of the board and principal operating officials of the centers;

(iv) Adopting policy for financial management practices, including a system to assure accountability for center resources, approval of the annual project budget, center priorities, eligibility for services, including criteria for partial payment schedules, and long-range financial planning;

(v) Evaluating center activities, including services utilization patterns, productivity of the center, patient satisfaction, achievement of project objectives, and development of a process for hearing and resolving patient grievances;

(vi) Assuring that the center is operated in compliance with applicable Federal, State, and local laws and regulations; and

(vii) Adopting health care policies including scope and availability of services, location and hours of services, and quality assurance procedures.

§ 56.305 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which, in his judgment, will provide needed health services in a catchment area which will not be served by another project funded under this part and meet the applicable requirements of section 319(d)(1)(A) of the Act and this part, in accordance with priorities established pursuant to section 319(b) of the Act and § 56.107 of Subpart A of this part: *Provided,* That in the case of applicants which propose to serve substantially the same catchment area or where available funds are insufficient to fund all approvable applications within a priority category specified in § 56.107, the Secretary will award grants to the applicants which, in his judgment, will best promote the purpose of section 319(d)(1)(A) of the Act and the applicable regulations of this part, taking into account with respect to each application:

(1) The extent to which the project would provide for the elements set forth in § 56.303;

(2) The capability of the applicant to provide quality health care services;

(3) The soundness of the financial management plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(4) The administrative and management capability of the applicant;

(5) The capability of the applicant to provide primary health services directly. In evaluating the relative capability of the applicant to provide such services directly, the Secretary shall take into consideration whether the

direct provision of such services is inappropriate because:

(i) Provision of such services through contract or other arrangement would be more cost-effective;

(ii) Provision of such services directly would unnecessarily duplicate existing resources; or

(iii) Provision of such services other than directly would enhance the accessibility or acceptability of such services to the population to be served.

(6) The degree to which the applicant intends to integrate services supported by a grant under this part with health services provided under other federally assisted health services or reimbursement programs or projects;

(7) The extent that community resources will be utilized by the project; and

(8) Consistent with the other requirements of this part, the degree to which and the manner in which the applicant provides specific health services which the Secretary has, through publication of a notice in the FEDERAL REGISTER, established as services which should receive emphasis by applicants.

Subpart D—Grants for Operating Migrant Health Entities

§ 56.401 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A of this part, are applicable to grants awarded pursuant to section 319(d)(1)(B) of the Act for the costs of operation of entities which intend to become migrant health centers and which provide health services to migratory agricultural workers, seasonal agricultural workers, and the members of their families in high impact areas.

§ 56.402 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 56.104 of Subpart A of this part,

(a) Be submitted by an entity which the Secretary determines intends to become a migrant health center but which will not, at the time of the grant award, meet one or more of the requirements of paragraphs (a) through (l) of § 56.303 of Subpart C of this part; and

(b) Contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of this part. Such information must include a plan which identifies which requirements of § 56.303 will not be met at the time of grant award and provides a timetable for and a detailed statement of the means to be employed in meeting those requirements.

§ 56.403 Project elements.

A project for the operation of a migrant health entity supported under this subpart must:

(a) Meet all of the requirements of § 56.303 of this part, *Provided*, That the project will not be required to meet the requirements of paragraphs (c), (h), (i), or (n) of such section if the Secretary finds that meeting any such requirement is not feasible or practical at the time of grant award.

(b) Provide those services enumerated in § 56.102(g)(1) of Subpart A of this part which are specified in the grant award.

(c) Meet the requirements of § 56.303 of Subpart C of this part by the end of the period of support under section 319(d)(1)(B) of the Act and this subpart, in accordance with the plan submitted under § 56.402(b) of this subpart.

§ 56.404 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purposes, the Secretary may award grants under this subpart to applicants therefor which, in his judgment, will provide needed health services in a catchment area not served by another project funded under this part and meet the applicable requirements of section 319(d)(1)(B) of the Act and this part, in accordance with the priorities established pursuant to section 319(b) of the Act and § 56.107 of Subpart A of this part; *Provided*, That in the case of applicants which propose to serve substantially the same catchment area or where available funds are insufficient to fund all approvable applications within a priority category specified in § 56.107, the Secretary will award the grant to the applicants which, in his judgment, will best promote the purposes of section 319(d)(1)(B) of the Act and the applicable regulations of this part, taking into account with respect to each application:

(1) The degree to which the project would provide the services enumerated in § 56.102(g)(1) and the feasibility of its providing all of such enumerated services by the end of the period of support under section 319(d)(1)(B) of the Act and this subpart;

(2) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other federally assisted health service or reimbursement programs or projects;

(3) The capability of the project to provide quality health care services;

(4) The administrative and management capability of the applicant; and

(5) The capability of the applicant to provide primary health services directly. In evaluating the relative capability of the applicant to provide such services directly, the Secretary shall take into consideration whether the direct provision of services is inappropriate because:

(i) Provision of such services through contract or other arrangement would be more cost-effective;

(ii) Provision of such services directly would unnecessarily duplicate existing resources; or

(iii) Provision of the services other than directly would enhance the accessibility or acceptability of the services to the population served.

(6) The extent to which community resources will be utilized by the project; and

(7) Consistent with the other requirements of this part, the degree to which and the manner in which the applicant provides specific health services which the Secretary has, through publication of a notice in the FEDERAL REGISTER, established as services which should receive emphasis by applicants.

(b) The Secretary shall:

(1) Make no more than two grants for the same entity under section 319(d)(1)(B) of the Act;

(2) Not make any grant under section 319(d)(1)(B) to an entity which, for the same project, has been awarded more than one grant under section 319(c) of the Act;

(3) Not make a grant under section 319(d)(1)(B) to an entity which has been awarded a grant under section 319(d)(1)(A) of the Act.

Subpart E—Grants for Planning and Developing Migrant Health Programs

§ 56.501 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A of this part, are applicable to grants awarded pursuant to section 319(c)(1)(B) of the Act for projects to plan and develop migrant health programs to provide health services to migratory agricultural workers, seasonal agricultural workers and the members of their families in areas in which no migrant health center exists and in which not more than 6,000 migratory agricultural workers and their families reside for more than two months.

§ 56.502 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 56.104 of Subpart A of this part,

(a) Be submitted for a project within a catchment area which

(1) Is not served, in whole or in part, by a migrant health center, and

(2) Has not more than 6,000 migratory agricultural workers and members of their families residing therein for more than 2 months per year; and

(b) Contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of this part.

§ 56.503 Project elements.

A project for the planning and development of a migrant health program supported under this subpart must:

(a) Determine (by survey or other appropriate means) the approximate number of

(1) Migratory agricultural workers and the members of their families, and

(2) Seasonal agricultural workers and the members of their families within the project's catchment area in the calendar year in which the grant is made and the period of time these workers and their families reside in the catchment area during such year.

(b) Prepare an assessment of need of the population proposed to be served by the migrant health program for the services set forth in § 56.603(a) of Subpart F of this part. This assessment of need must, at a minimum, consider the factors listed in § 56.104(b)(3) (i)-(iv).

(c) Design a migrant health program for such population, based on such assessment, which indicates in detail how the proposed program will fulfill the needs identified in that assessment and meet the requirements of Subpart F of this part.

(d) Develop a plan for the implementation of the program designed pursuant to paragraph (c) of this section. The implementation plan must provide for the time-phased recruitment and training of the personnel essential for the operation of a migrant health program and the gradual assumption of operational status of the project so that the project will, in the judgment of the Secretary, meet the requirements of Subpart F of this part as of the end of the project period.

(e) Implement the plan developed pursuant to paragraph (d) of this section in accordance with such paragraph.

(f) Make efforts to secure within the proposed catchment area of such project, to the extent possible, financial and professional assistance and support for the project.

(g) Initiate and encourage continuing community involvement in the development and operation of the project through, for example, contributions or loans of cash, services, equipment, full- or part-time staff, space, materials, or facilities.

(h) Provide for sufficient staff, qualified by training and experience, to carry out the project and establish standards and qualifications for personnel (including the project director).

(i) Utilize, to the maximum extent feasible, other Federal, State, local, and private resources available for support of the project, prior to use of project funds under this subpart.

(j) Provide for the means of evaluating the project's progress in achievement of its specific objectives and submission of such progress reports on the project as the Secretary may from time to time request.

§ 56.504 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which, in his judgment, will provide needed health services in a catchment area not served by another project funded under this part and meet the applicable requirements of section 319(c)(1)(B) of the Act and this part, in accordance with priorities established pursuant to section 319(b) of the Act and § 56.107 of Subpart A of this part; *Provided*, That in the case of applicants which propose to serve substantially the same catchment areas or where available funds are insufficient to fund all approvable applications within a priority category specified in § 56.107,

(1) Priority shall be given to applications submitted by community-based organizations which are representative of the population to be served by the project. For purposes of this paragraph, an applicant shall be deemed to be such an organization if it provides a formal mechanism (such as membership on the organization's governing body or membership on an advisory body) which gives migratory and seasonal agricultural workers and their families significant involvement in the formulation of the organization's policies; and

(2) Where all such applicants are community-based organizations representative of the population to be served by the project, the Secretary shall award the grant to the applicants which will, in his judgment, best promote the purposes of section 319(c)(1)(B) of the Act and the appli-

cable regulations of this part, taking into account with respect to each application:

(i) The degree to which the proposed project satisfactorily provides for the elements set forth in § 56.203;

(ii) The administrative and management capability of the applicant;

(iii) The extent to which community resources will be utilized in the project; and

(iv) The degree to which the applicant intends to integrate services supported by a grant under this part with health services provided under other federally assisted health services or reimbursement programs or projects.

(b) The Secretary shall award no more than one grant under this subpart for the same project.

Subpart F—Grants for Operating Migrant Health Programs

§ 56.601 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A of this part, are applicable to grants awarded pursuant to section 319(d)(1)(C) of the Act for projects for operating programs to provide health services to migratory agricultural workers, seasonal agricultural workers and the members of their families in areas in which no migrant health center exists and in which not more than 6,000 migratory agricultural workers and their families reside for more than two months.

§ 56.602 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 56.104 of Subpart A of this part,

(a) Be submitted for a project with a catchment area which

(1) Is not served, in whole or in part, by a migrant health center, and

(2) Has not more than 6,000 migratory agricultural workers and the members of their families residing therein for more than two months per year; and

(b) Contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of this part.

§ 56.603 Project elements.

A project for operating a migrant health program supported under this subpart must:

(a) Provide to migratory and seasonal agricultural workers and the members of their families in its catchment area one or more of the following groups of services so that such services are available and accessible promptly as appropriate, and in a manner which will assure continuity of care, as approved by the Secretary and set forth (including specific services to be provided) in the grant award:

(1) Emergency health care, including diagnostic and treatment services in an ambulatory health care setting or hospital and dental services for the alleviation of acute pain and suffering for medical emergencies, when provision of such services is necessary to avoid jeopardizing the patient's condition until appropriate services from other providers can reasonably be obtained;

(2) Primary care;

(3) Arrangements with existing health care facilities to furnish primary health services (other than primary care);

(4) Other services set forth in § 56.102(g)(1) which are needed to improve the health of such individuals.

(b) Implement a system for maintaining the confidentiality of patient records in accordance with the requirement of § 56.111 of Subpart A of this part.

(c) Develop management and control systems which are in accordance with sound financial management procedures, including the provision for an audit conducted in accordance with the DHHS Audit Agency Guide for Audits of Migrant Health Grants, as amended, on at least an annual basis (unless waived for cause by the Secretary), by an independent certified public accountant or public accountant licensed before December 31, 1970, to determine, at a minimum, the fiscal integrity of grant financial transactions and reports and compliance with the regulations of this part and the terms and conditions of the grant.

(d) When the cost of care and services furnished by or through the project is to be reimbursed under Title XIX or Title XX of the Social Security Act, obtain or make every reasonable effort to obtain a written agreement with the Title XIX or Title XX State agency for such reimbursement.

(e) Have prepared a schedule of fees or payments for the provision of its services designed to cover its reasonable costs of operation and a corresponding schedule of discounts adjusted on the basis of the patient's ability to pay. The schedule of discounts must provide for a full discount to individuals and families with annual incomes at or below those set forth in the most recent CSA Poverty Income Guidelines (42 CFR 1060.2) (except that nominal fees for service may be collected from individuals and families with annual incomes at or below such levels if imposition of such fees is consistent with project goals) and for no discount to individuals and families with annual incomes greater than twice those set forth in the Guidelines.

(f) Make every reasonable effort, including the establishment of systems for eligibility determination, billing, and collection, to

(1) Collect reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under Title XVIII of the Social Security Act, to medical assistance under a State plan approved under Title XIX of such Act, to social services and family planning under Title XX of such Act, or to assistance for medical expenses under any other public assistance program, grant program, or private health insurance or benefit program on the basis of the schedule of fees prepared pursuant to paragraph (e) of this section without application of any discounts, and

(2) Secure from patients payments for services in accordance with the schedule of fees and discounts required by paragraph (e) of this section.

(g) Develop an overall financial management plan and an operating budget for the project which include and identify, in accordance with generally accepted accounting principles, all anticipated current income and expense items and capital income and expense items, if any.

(h) Establish basic statistical data, cost accounting, management information, and reporting or monitoring systems which will meet the project's management needs and shall enable the project to provide such statistics and other information as the Secretary may reasonably require relating to the project's costs of operation, patterns of utilization of services, and the availability, accessibility, and acceptability of its services, and to make such reports to the Secretary in a timely manner with such frequency as the Secretary may reasonably require.

(i) Review its catchment area annually to insure that the criteria set out in § 56.104(b)(2) are met and, where such criteria are not met, revise its catchment area, with the approval of the Secretary, to conform with such criteria to the extent feasible.

(j) In the case of a project which serves a population including a substantial proportion of individuals of limited English-speaking ability, have a plan and made arrangements responsive to the needs of these populations for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and have identified an individual on its staff who is fluent in both that language and in English and whose responsibilities include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences. If more than one non-English language is spoken by such group or groups, an individual or individuals fluent in those languages and English must be so identified.

(k) Be operated in a manner calculated to preserve human dignity and to maximize acceptability and effective utilization of services.

(l) To the extent possible, coordinate and integrate project activities with the activities of other federally funded, as well as State and local, health services delivery projects and programs serving the same population.

(m) Establish means for evaluating progress toward the achievement of the specific objectives of the project.

(n) Provide sufficient staff, qualified by training and experience, to carry out the activities of the project.

(o) Assure that facilities utilized in the performance of the project meet applicable fire and life safety codes.

(p) Utilize, to the maximum extent feasible, other Federal, State and local, and private resources available for support of the project, prior to use of project funds under this part.

(q) Provide for community participation through, for example, contributions of cash or services, loans of full- or part-time staff, equipment, space, materials, or facilities, and, to the extent feasible, establishment of an advisory council to advise with respect to the overall management of the project including services to be provided, the manner of their provision, and appointment of personnel. The membership of such advisory council shall be representative of the population to be served in terms of appropriate demographic characteristics, such as race, sex, and ethnicity.

(r) Where the project will provide services through contract or other cooperative arrangements with other providers of services, the project must

(1) Enter into any such contract or arrangement only if the provider of services will provide the services in a timely manner and make the services accessible and acceptable to the population to be served; and

(2) Make payment for services so provided in accordance with a schedule of rates and payment procedures established and maintained by the project. The project must be prepared to substantiate that such rates are reasonable and necessary.

(s) Operate in a manner such that no migratory or seasonal agricultural worker or member of their families will be denied service by reason of his or her inability to pay therefor. *Provided, however,* That a charge for the provision of services will be made to the extent that a third party (including a Government agency) is authorized or is under legal obligation to pay such charges.

(t) Have an ongoing quality assurance program as described in § 56.303(c) except as the Secretary finds that such a program would not be feasible.

§ 56.604 Grant evaluation and award.

(a) Within the limit of funds determined by the Secretary to be available the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, provide needed health services in a catchment area which will not be served by another project funded under this part and meet the applicable requirements of section 319(d)(1)(C) of the Act and this subpart, in accordance with priorities established pursuant to section 319(b) of the Act and § 56.107 of Subpart A of this part; *Provided,* That in the case of applicants which propose to serve substantially the same catchment areas or where available funds are insufficient to fund all approvable applications within a priority category specified in § 56.107,

(1) Priority shall be given to applications submitted by community-based organizations which are representative of the population to be served by the project. For purposes of this paragraph, an applicant shall be deemed to be such an organization if it provides a formal mechanism (such as membership on the organization's governing body or membership on an advisory body) which gives migratory seasonal agricultural workers and their families significant involvement in the formulation of the organization's policies; and

(2) Where all such applicants are community-based organizations representative of the population to be served by the project, the Secretary shall award the grant to the applicants which will, in his judgment, best promote the purposes of section 319(d)(1)(C) of the Act and the applicable regulations of this part, taking into account with respect to each application:

(i) The degree to which the proposed project satisfactorily provides for the elements set forth in § 56.203;

(ii) The administrative and management capability of the applicant;

(iii) The extent to which community resources will be utilized in the project; and

(iv) The degree to which the applicant intends to integrate services supported by a grant under this part with health services provided under other federally assisted health services or reimbursement programs or projects.

Subpart G—Grants for Technical Assistance

§ 56.701 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A of this part except as otherwise set forth herein, are applicable to grants awarded pursuant to section 319(g) of the Act for the provision of technical and other non-financial assistance to grantees under sections 319(c)(1)(A), 319(d)(1)(A) and 319(d)(1)(B) of the Act.

§ 56.702 Application.

To be approved by the Secretary under this subpart, an application for a grant must meet the requirements of §§ 56.104(a), 56.104(b) (1), (4), (7), (10), and (11), and 56.104(c) of Subpart A of this part.

§ 56.703 Project elements.

A project for the provision of technical assistance to migrant health centers and entities which intend to become migrant health centers which is supported under this subpart must:

(a) Provide to such centers and entities as are specified in the grant award, such technical and other nonfinancial assistance (such as fiscal and program management assistance or training of the staff of such center or entity in such management) as may be specified in the grant award. Such technical or other nonfinancial assistance shall be designed to assist such centers and entities in

(1) Developing plans for becoming migrant centers; and/or

(2) Meeting the requirements of sections 319(f)(2) of the Act.

(b) Provide such assistance through its own staff or resources.

(c) Where the project will provide training to the staff of a center or entity in management or the provision of health services, provide such training consistent, as applicable, with § 56.108(b)(7).

(d) Maintain such records and make such reports on the expenditure of funds under this subpart and provision of such assistance as the Secretary may require.

§ 56.704 Grant evaluation and award.

Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 319(g) of the Act and applicable regulations of this part, taking into consideration

(a) The cost-effectiveness of the application; and

(b) The number of centers and entities to be served by the applicant.

Subpart H—Acquisition and Modernization of Existing Buildings

§ 56.801 Applicability of 42 CFR Part 51c, Subpart E.

The provisions of 42 CFR Part 51c, Subpart E, establishing requirements for the acquisition and modernization of existing buildings, shall apply to all grants under section 319 of the Act for project costs which include the cost of acquisition and/or modernization of existing buildings (including the cost of amortizing the principal of, and paying the interest on, loans); except that, for purposes of this Subpart, references within Subpart E to Part 51c, or to subparts of Part 51c, shall be deemed to be references to Part 56, or to the appropriate subparts of Part 56, and references to section 330 of the Act shall be deemed to be references to section 319 of the Act.

[43 FR 5353, Feb. 7, 1978]

PART 57—GRANTS FOR CONSTRUCTION OF TEACHING FACILITIES, EDUCATIONAL IMPROVEMENTS, SCHOLARSHIPS AND STUDENT LOANS

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Subpart A—[Reserved]

Subpart B—Grants for Construction of Teaching Facilities for Health Professions Personnel

AUTHORITY: Sec. 727, 77 Stat. 170; 42 U.S.C. 293g.

SOURCE: 37 FR 20543, Sept. 30, 1972, unless otherwise noted.

§ 57.101 Applicability.

The regulations in this part are applicable to the award of grants under Part B of title VII of the Public Health Service Act for construction of teaching facilities for medical, dental, and other health personnel (42 U.S.C. 293 et seq.).

§ 57.102 Definitions.

As used in this subpart:

(a) All terms not defined herein shall have the same meaning as given them in section 724 of the Act.

(b) "Act" means the Public Health Service Act, as amended.

(c) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(d) "Council" means the National Advisory Council on Health Professions Education (established pursuant to section 725 of the Act).

(e) "Construction grant" and "grant" mean a grant of funds for the construction of an approved project as authorized under Part B of title VII of the Act, and in accordance with these regulations.

(f) "Affiliated hospital" or "affiliated outpatient facility" means a hospital or outpatient facility (as defined in section 645 of the Act) which, although not owned by such school, has a written agreement with a school of medicine, osteopathy or dentistry eligible for assistance under this subpart, providing for effective control by the school of the teaching in the hospital or outpatient facility.

(g) "New school" means a school which, at the time of filing an application for a construction grant under this subpart, has not graduated a class

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because of an insufficient period of operation.

(h) "Equipment" includes those items which are necessary for the functioning of the facility or portion thereof with respect to which the grant is made, but does not include items of current operating expense or consumed in use such as glassware, chemicals, food, fuel, drugs, paper, printed forms, books, pamphlets, periodicals and disposable housekeeping items.

(i) "Advanced education" means training in the health sciences beyond the first professional degree or equivalent degree, and such training related thereto. Such training may include internships and residencies, and work toward masters and Ph. D. degrees.

(j) "Continuing education" means training for which no degree is awarded and in which health professions personnel participate in order to enhance their skills, and may include refresher courses, seminars, and the like.

(k) "Multipurpose facilities" means facilities which are primarily for teaching purposes, but which are also for research, or research and related purposes, in the sciences related to health (within the meaning of Part A of title VII of the Act) or for medical library purposes (within the meaning of Part J of title III). The Secretary may determine "to be primarily for teaching purposes" any facilities with respect to which he determines that the health professions teaching portions of such facilities, including research and library space essential for teaching purposes, will substantially exceed the total of the research and library portions which are not essential for teaching taken together.

(l) "Completion of construction" means that date on which the Secretary determines, on the basis of certification by the grantee, that the project is completed: *Provided, however,* In the event the grantee occupies the project prior to the date of such certification, the Secretary shall be immediately notified of such occupancy, and "completion of construction" shall be deemed to have occurred with respect to the project as of the date of such occupancy.

§ 57.103 Eligibility.

In order to be eligible for a construction grant under Part B of the Act, the applicant shall:

(a) Meet the applicable requirements of section 721(b) of the Act;

(b) Be a public or nonprofit private school of medicine, dentistry, osteopathy, pharmacy, optometry, podiatry, veterinary medicine, public health, or any combination thereof, or an affiliated hospital or affiliated outpatient facility;

(c) Be located in a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Canal Zone, American Samoa, the Trust Territories of the Pacific Islands or Guam;

(d) Except in the case of an application with respect to an affiliated hospital or affiliated outpatient facility, be accredited by a recognized body or bodies approved for such purpose by the Commissioner of Education, except that a new school which (by reason of no, or an insufficient period of, operation) is not, at the time of making application for the construction grant, eligible for accreditation by such recognized body or bodies shall be deemed accredited for purposes of receiving a grant if the Commissioner finds, after consultation with the appropriate accreditation body or bodies, that there is reasonable assurance that the school, after completion of the facility and at or prior to the time of graduation of the first class to use such facility, will have met the accreditation standards of such body or bodies: *Provided,* That, in the case of an application from a combination of schools, each constituent school must meet the requirements of this paragraph;

(e) In the case of an application with respect to an affiliated hospital or outpatient facility, have its application approved by the school of medicine, osteopathy, or dentistry with which the hospital or outpatient facility is affiliated;

(f) In the case of an application with respect to the construction of multipurpose facilities, provide evidence satisfactory to the Secretary that such facilities will be used primarily for teaching purposes, and that such facilities are otherwise eligible under Part B of title VII of the Act;

(g) In the case of a project for the construction of a facility intended, at least in part, for the provision of health services, provide an opportunity for comment with respect to such project to

(1) The State agency administering or supervising the administration of the State plan approved under section 314(a), and

(2) The public or nonprofit private agency or organization responsible for the plan or plans referred to in section 314(b) and covering the area in which such project is to be located or if there is no such agency, such other public or nonprofit private agency or organization (if any) as performs, as determined in accordance with criteria of the Secretary, similar functions;

(h) In the case of an application with respect to interim facilities, provide assurance satisfactory to the Secretary that such facilities are designed to provide teaching space on a short-term (less than 10 years) basis while facilities of a more permanent nature are being planned and constructed;

(i) Provide its assessment of the environmental impact of the project as called for by section 102(2)(c) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(c));

(j) Furnish its evaluation of the project site in accordance with the terms and provisions of E.O. 11296, 31 FR 10663 (August 10, 1966) relating to the evaluation of flood hazards in locating federally owned or financed facilities.

§ 57.104 Priority.

(a) Priority in approving applications for construction grants shall be determined in accordance with the factors specified in section 721(d) of the Act, and the following:

(1) The relative need for increased enrollment and the availability of students;

(2) The relative effectiveness of the project in accomplishing the purposes of the Act at the least relative cost to the Federal Government;

(3) The relative ability of the applicant to make efficient and productive use of the facility constructed; and

(4) Such other pertinent factors as the Secretary may specify;

(b) The Secretary shall give special consideration to grant applications to assist in the construction of new schools of medicine, osteopathy, and dentistry, where such applications contain or are reasonably supported by assurances that, because of use by such school of existing facilities (including Federal medical or dental facilities), the school will be able to accelerate the date on which it will begin its teaching program.

§ 57.105 Percentage of participation; amount of construction grant.

(a) *Percentage of maximum participation.* (1) The amount of any construction grant made under Part B of title VII of the Act and pursuant to this subpart may not exceed 70 percent of the necessary cost of construction of a project as determined by the Secretary, except:

(i) In the case of a project with respect to a school of public health, the amount of such grant may not exceed 75 percent of the necessary cost of construction; and

(ii) In the case of (*a*) a project with respect to a new school; (*b*) a project constituting new facilities which will result in a major expansion of training capacity at an existing school in accordance with paragraph (a)(2) of this section; (*c*) all or so much of a project constituting a major remodeling or renovation of an existing facility which is required by a school to meet an increase in student enrollment; or (*d*) any other project where the Secretary determines that unusual circumstances require a larger percent of participation in order to carry out the intent of Part B of title VII of the Act the amount of such grant may not exceed 80 percent of the necessary cost of construction.

(2) For purposes of paragraph (a)(1) of this section:

(i) A major expansion of training capacity at an existing school shall be construed to mean that the full-time first-year enrollment at such school, upon completion of construction, will exceed the highest full-time first-year enrollment at such school for any of the 5 full school years preceding the year in which the application for a construction grant is made by not less than 40 students or 40 percent, whichever is greater: *Provided, however,* That where the Secretary determines with respect to a particular school that such increased enrollment cannot be achieved until the second or third full school year after completion of construction, he may determine that the requirements for a major expansion of training capacity are met for each of the first or second full school years after completion of construction, if during such first or second full school year the increase in first-year enrollment will equal such amount in excess of 5 percent or five students, whichever is greater, as the Secretary may specify;

(ii) A major remodeling or renovation of a facility shall include only that portion of remodeling or renovation which is necessary to meet an increase in student enrollment, which increase shall be construed to mean that, during the first full school year after completion of construction and for each of the 9 school years thereafter the first-year enrollment will exceed the highest first-year enrollment at such school for any of the 5 full school years preceding the year in which the application is made by not less than the mandatory increase as provided for under section 770(f)(1)(A) of the Act;

(iii) Unusual circumstances may be determined by the Secretary to exist:

(*a*) Where a school is located in a geographical area of the United States with a critical shortage of health profession manpower (as determined by the Secretary with the advice of Council);

(*b*) Where the project is found to be necessary to prevent the curtailment of enrollment at a school;

(*c*) Where the project is essential to the securing or maintenance of a school's accreditation; or

(*d*) Where there are other relevant factors consistent with this subpart and the purposes of Part B of title VII of the Act.

(b) *Amount of construction grant—less than maximum.* In determining the amount of a construction grant within the percentage limitations as set forth in paragraph (a) of this section, the Secretary shall take into consideration the most effective use of available Federal funds to further the purposes of Part B of title VII of the Act, and the needs of the applicant.

§ 57.106 Nondiscrimination.

(a) *Executive Order 11246.* Each construction contract under this subpart is subject to the condition that the applicant shall comply with the requirements of Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, relating to nondiscrimination in construction contract employment, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

(b) *Civil Rights Act of 1964.* Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.), which provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination, under any program or activity receiving Federal financial assistance. A regulation implementing such Title VI, which is applicable to grants made under this part, has been issued by the Secretary with the approval of the President (45 CFR Part 80).

(c) *Discrimination on the basis of sex prohibited.* Attention is called to the requirements of section 799A of the Act, and to 45 CFR Part 83 which together provide that the Secretary may not make a grant, loan guarantee, or interest subsidy payment under title VII of the Act to, or for the benefit of, any school of medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, podiatry, or public health, or any training center for allied health personnel or to any other entity unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary that the school, training center or other entity will not discriminate on the basis of sex in the admission of individuals to its training programs.

§ 57.107 Terms and conditions.

In addition to any other requirements imposed by law or determined by the Secretary to be reasonably necessary with respect to particular projects to fulfill the purpose of the grant, each construction grant shall be subject to the condition that the applicant shall furnish and comply with the following assurances:

(a) *Title.* That applicant has a fee simple or such other estate or interest in the site, including necessary easements and rights-of-way, sufficient to assure for a period of not less than 20 years (or in the case of interim facilities for the period constituting the estimated useful life of such facilities) undisturbed use and possession for the purpose of the construction and operation of the facility;

(b) *Competitive bids.* (1) That the approval of the Secretary shall be obtained before the project is advertised or placed on the market for bidding and that such approval shall include a determination by the Secretary that the final plans and specifications conform to the minimum standards of construction and equipment as set forth in Appendix A of these regulations.

(2) That, except as otherwise provided by State or local law, all contracting for construction (including the purchase and installation of built-in equipment) shall, except as provided in paragraph (b)(3) of this section, be on a lump sum fixed-price basis, and contracts will be awarded on the basis of competitive bidding obtained by public advertising with award of the contract to the lowest responsive and responsible bidder. The provision for exceptions based on State or local law shall not be invoked to give local contractors or suppliers a percentage preference over non-local contractors bidding for the same contract. Such practices are precluded by this paragraph.

(3) A substitute bidding procedure of selective solicitation with response from three or more bidders may be used if:

(i) The applicant requests and justifies the use of the procedure;

(ii) The procedure is consistent with State and local laws; and

(iii) The Secretary determines that it is necessary to limit bidding to contractors of proven competence due to the complexity or specialty of the project or that the time element is of primary consideration. When this bidding procedure is used, the applicant shall establish reasonable bid prequalification standards for contractors. The applicant shall then accept and consider bids from any contractor who requests permission to bid and who is determined by the applicant to meet these prequalification standards. Adequate time (normally 30 days) shall be allowed for contractors to prepare bids, and award of construction contracts shall be made to the lowest qualified and responsible bidder whose bid is considered fully responsive to the bid invitation;

(c) *Approval of estimated cost.* That applicant will enter into no construction contract or contracts with respect to the project or any portion thereof where the costs exceed estimates in the application for such work, without prior approval of the Secretary.

(d) *Relocation assistance.* That in the case of a public applicant with an approved project which involves the displacement of persons or businesses, on and after January 2, 1971, whose real property has or will be taken, the applicant will comply with the provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Pub. L. 91-646) and the applicable regulations issued thereunder; (45 CFR Part 15, as added by 36 FR 18838 (Sept. 22, 1971));

(e) *Cost in excess of approved costs.* That applicant will finance all costs in excess of the estimated costs approved in the application and submit to the Secretary for prior approval any changes that substantially alter the scope of its education program, or of the work, functions, utilities, or safety of the facility:

(f) *Completion responsibility.* That applicant will construct the project, or cause it to be constructed, to final completion in accordance with the grant application and the plans and specifications;

(g) *Records and accounts.* That applicant will maintain adequate and separate accounting and fiscal records and accounts for all funds provided from any source to pay the cost of the project, and permit audit of such records and accounts at any reasonable time. All records will be retained for 3 years after the close of the fiscal year in which the construction is completed. Such records may be destroyed at the end of such 3-year period if the applicant has been notified of the completion of the Federal audit by such time. If the applicant has not been so notified by the end of such 3-year period, such records will be retained (1) for 5 years after the close of the fiscal year in which the construction is completed or (2) until the grantee is notified of the completion of the Federal audit, whichever is earlier. In all cases where audit questions have arisen before the expiration of such 5-year period, records shall be retained until resolution of such questions;

(h) *Progress reports.* That applicant shall furnish progress reports and such other information as the Secretary may require;

(i) *Construction supervision.* That applicant shall provide and maintain competent and adequate architectural or engineering supervision and inspection at the construction site to insure that the completed work conforms with the plans and specifications;

(j) *Non-Federal share.* That sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility;

(k) *Funds for operation.* That sufficient funds will be available after construction is completed for effective use of the facility for the purposes for which it is being constructed;

(l) *Authorized uses.* That the facility is intended to be used for the purposes for which the application has been made;

(m) *Prohibition against religious use.* That no portion of the facility constructed with funds under Part B of title VII of the Act will be used for sectarian instruction or as a place for religious worship for so long as such facility has substantial value;

(n) *Expansion of training capacity.* That in the case of any application (including an application with respect to continuing education or advanced training) to expand the training capacity of an existing school, the first-year enrollment at such school during the first full year after the completion of the construction and for each of the 9 school years thereafter will exceed the highest first-year enrollment at such school for any of the 5 full years preceding the year in which the application is made by at least 5 percent of such highest first-year enrollment, or by five students, whichever is greater. This increase shall be in addition to any increase assured pursuant to section 770(f)(1)(A) of the Act: *Provided, however,* That if such school is not required to meet in the fiscal year in which the application is made the enrollment increase prescribed under section 770(f)(1)(A) of the Act because of limitations of physical facilities available to the school for training, the Secretary may, after consulation with the Council, waive all or any portion of such requirements provided for in this paragraph, if the application contains or is supported by reasonable assurances satisfactory to the Secretary that the number of first-year students enrolled at such school during the first full school year after the completion of such project and for each of the next 9 school years thereafter shall be not less than the number of first-year students that such school would be required to enroll for a grant under section 770(f) of the Act (without regard to paragraph (2) thereof) for a grant under section 770(a) of the Act;

(o) *New school construction.* That in the case of a project for the construction of a new school,

(1) The first-year enrollment at such school during the third full school year after completion of construction and for each of the seven school years thereafter shall be that number which is set forth in the application as the projected total first-year enrollment of the school and which is determined by the Secretary to be adequate in relation to the amount of the grant,

taking into consideration the most effective use of the total amount of Federal funds available, the amount of funds requested by the applicant, the nature and the quality of training to be provided in the facility, and other relevant factors; and

(2) The first-year enrollment at such school during the first full school year after completion of construction will be at least one-third of the number determined pursuant to paragraph (o)(1) of this section;

(p) *Wage rate standards.* That any laborer or mechanic employed by any contractor or subcontractor in the performance of work on the construction of the facility shall be paid wages at rates not less than those prevailing on similar construction in the locality as determined under the Davis-Bacon Act (40 U.S.C. 276 et seq.) and shall receive compensation at a rate not less than 1 1/2 times his basic rate of pay for all hours worked in any workweek in excess of 8 hours in any calendar day or 40 hours in the workweek (40 U.S.C. 327-332);

(q) *Clearinghouse review.* That the applicant has, at the earliest feasible time, notified the planning and development clearinghouse of the State and the region, if there is one, or of the metropolitan area in which the project is to be located, of its intent to apply for a grant under this subpart, and of the nature of the project for which assistance has been sought, including a summary description of such project; any comments received by the applicant from the clearinghouse pursuant to such notification shall be considered by the applicant and shall be included in or attached to the application;

(r) *Accessibility by handicapped.* That the applicant shall require the facility to be designed to comply with the "American Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped," Number A117.1-1961, as modified by other standards prescribed by the Secretary or the Administrator of General Services. The applicant shall be responsible for conducting inspections to insure compliance with these specifications by the contractor; and

(s) *Minimum standards of construction and equipment.* That the plans and specifications for the project will conform to the minimum standards of construction and equipment as set forth in Appendix A of this subpart.

The Secretary may at any time approve exceptions to the foregoing terms and conditions where he finds that such exceptions are not inconsistent with Part B of title VII of the Act and purposes of the program.

§ 57.108 Construction contract requirements.

The following conditions and provisions must be included in all construction contracts:

(a) The provisions set forth in "DHHS Requirements for Federally Assisted Construction Contracts Regarding Labor Standards and Equal Employment Opportunities", Form DHHS 514 (April, 1969) (issued by the Office of Grants Administration Policy, U.S. Department of Health and Human Services) pertaining to the Davis-Bacon Act, the Contract Work Hours Standards Act, and the Copeland Act (Anti-Kickback) Regulations, except in the case of contracts in the amount of $2,000 or less; and pertaining to Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, relating to nondiscrimination in construction contract employment, except in the case of contracts in the amount of $10,000 or less;

(b) The contractor shall furnish performance and payment bonds, each of which shall be in the full amount of the contract price, and shall maintain, during the life of the contract, adequate fire, workmen's compensation, public liability, and property damage insurance: *Provided however,* That in the case of a State or local unit of government which enters into a construction contract of less than $100,000, State or local provisions with respect to performance and payment bonds shall be deemed to meet the requirements of this paragraph; and

(c) The Secretary shall have access at all reasonable times to work wherever it is in preparation or progress, and the contractor shall provide proper facilities for such access and inspection.

§ 57.109 Good cause for other use of completed facility.

If, within 20 years after completion of construction (or, in the case of interim facilities prior to the time at which teaching in such facilities is moved to a permanent facility, whichever comes first), the facility shall cease to be used for any one or more of the purposes for which it was constructed, the Secretary, in determining whether there is good cause for releasing the applicant or other owner of the facility from the obligation so to use the facility, shall take into consideration the extent to which:

(a) The facility will be devoted by the applicant or other owner to the teaching of other health personnel, or to other purposes in the sciences related to health for which funds are available under Part B of title VII of the Act and these regulations;

(b) A hospital or outpatient facility will be used as provided for under title VI of the Act;

(c) There are reasonable assurances that for the remainder of such period other facilities not previously utilized for teaching health professions personnel, or for research and related purposes in the sciences related to health, or for medical library purposes, as the case may be, will be so utilized and are substantially the equivalent in nature and extent for such purposes.

§ 57.110 Acquisition of facilities.

In addition to the other requirements of this subpart the following provisions are also applicable to the acquisition of existing facilities:

(a) *Minimum standards of construction and equipment.* That a determination by the Secretary that the facility conforms (or upon completion of any necessary construction will conform) to the minimum standards of construction and equipment as set forth in Appendix A of this subpart, shall be obtained before entering into a final or unconditional contract for such acquisition. Where the Secretary finds that exceptions to or modification of any such minimum standards of construction and equipment would be consistent with the purposes of Part B of title VII of the Act and of the program, he may authorize such exceptions or modifications;

(b) *Estimated cost of acquisition and remodeling: suitability of facility.* Each application for a project involving the acquisition of existing facilities shall include in the detailed estimates of the cost of the project, the cost of acquiring such facilities, and any cost of remodeling, renovating or altering such facilities to serve the purposes for which they are acquired. Such application shall demonstrate to the satisfaction of the Secretary that the architectural, structural and other pertinent features of the facility, as modified by any proposed expansion, remodeling, renovation, or alteration, will be clearly suitable for the purposes of the program, and, to the extent of the costs in which Federal participation is requested, are not in excess of what is necessary for the services proposed to be provided in such facilities;

(c) *Determination of necessary cost.* The necessary cost of acquisition of existing facilities will be determined on the basis of such documentation submitted by the applicant as the Secretary may prescribe (including the reports of such real estate appraisers as the Secretary may approve) and other relevant factors;

(d) *Bona fide sale.* Federal participation in the acquisition of existing facilities is on condition that such acquisition constitutes a bona fide sale involving an actual cost to the applicant and will result in additional or improved facilities for purposes of the program; and

(e) *Facility which has previously received Federal grant.* No grant for the acquisition of a facility which has previously received a Federal grant for construction, acquisition, or equipment shall serve either to reduce or restrict the liability of the applicant or any other transferor or transferee from any obligation of accountability imposed by the Federal Government by reason of such prior grant.

§ 57.111 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interest of public health or the conservation of grant funds.

§ 57.112 Early termination and withholding of payments.

Whenever the Secretary finds that a grantee has failed in a material respect to comply with the applicable provisions of the Act, the regulations of this subpart or the terms of the grant, he may, on reasonable notice to the grantee, withhold further payments, and take such other action, including the termination of the grant, as he finds appropriate to carry out the purposes of the applicable provisions of the Act and regulations. Noncancellable obligations of the grant properly incurred prior to the receipt of the notice of termination will be honored. The grantee shall be promptly notified of such termination in writing and given the reasons therefor.

APPENDIX A—MINIMUM STANDARDS OF CONSTRUCTION AND EQUIPMENT

The minimum standards of construction and equipment set forth below have been established by the Secretary as required by section 727 of the Act. In accordance with 5 U.S.C. 552(a)(1), the publications to which reference is made in this Appendix A, unless otherwise indicated, are hereby incorporated by reference and made a part hereof. These documents are available for inspection at the Department's and Regional Offices' Information Centers listed in 45 CFR 5.31 and copies of such documents may be purchased as specified. These standards are applicable to all projects approved for construction grants under Part B of title VII of the Act; in addition, teaching hospitals and outpatient facilities are also required to comply with the requirements of "Minimum Requirements of Construction and Equipment for Hospital and Medical Facilities' (DHHS Publication No. (IBR)74-4000)" which document is incorporated by reference in § 53.101(a) of this chapter. Said document will be provided to all applicants with a need therefor, and is available to any interested person, whether or not affected by the provisions of this subpart, upon request to the Regional Office of the Department of Health and Human Services or the Public Inquiries Branch, Public Health Service, Washington, D.C.

(a) *General.* The structural design, construction, and fire safety provisions of all project facilities shall comply with the standards of the National Building Code, 1967 (available from American Insurance Association Engineering and Safety Department, 85 John Street, New York, NY 10038, or 120 South La Salle Street, Chicago, IL 60603, or 465 California Street, San Francisco, CA 94104) or with applicable State, local codes and ordinances, whichever is more restrictive.

(b) *Mechanical.* All installations of fuel burning equipment, steam, heating, air conditioning and ventilation, plumbing and other piping systems and boilers shall comply with the following standards:

(1) Handbook of Fundamentals: American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) 1972; United Engineer Center, 345 East 47th Street, New York NY 10017.

(2) National Standard Plumbing Code 1955; American Society of Mechanical Engineers (ASME); United Engineer Center, 345 East 47th Street, New York, NY 10017.

(3) Boiler and Pressure Vessel Code, 1971 edition, with current addenda, section 8, Division I. American Society of Mechanical Engineers (ASME); United Engineer Center, 345 East 47th Street, New York, NY 10017.

(c) *Fire and safety.* The fire-resistant design criteria for the facility will be governed by the criteria necessary for that portion of the facility which is subject to the most severe usage. Remodeled structures shall be upgraded, in total, unless it is feasible to isolate the improved portion of the building with fire walls and fire doors. Fire-resistant design shall be in accordance with the standards of Fire Safety Code Number 101, 1970, National Fire Protection Association, International, 60 Batterymarch Street, Boston, MA 02110.

(d) *Emergency electrical service.* Fire alarm systems and other electrical service shall conform to the standards as specified in Life Safety Code Number 101, 1970, National Fire Protection Association, International, 60 Batterymarch Street, Boston, MA 02110.

(e) *Electrical.* All electrical installations and equipment shall be in accordance with State and local codes and applicable sections of National Electric Code, NFPA Bulletin No. 70 HC, 1971, National Fire Protection Association, International, 60 Batterymarch Street, Boston, MA 02110.

(f) *Radiation protection.* All areas in which X-ray, gamma-ray, beta-ray producing and similar equipment is located shall be protected from radiation in accordance with the standards which are in the handbook reports No. 33, 1968; 34, 1970; 35, 1970, and 36,

BEST DOCUMENT AVAILABLE

1970, of the National Council on Radiation Protection and Measurement, Box 4867, Washington, DC 20008.

(g) *Earthquake.* All facilities shall be designed and constructed in accordance with the standard specified in the Uniform Building Code, 1970, International Conference of Building Officials, 50 South Los Robles, Pasadena, CA 91101, unless more restrictive State and local codes govern.

(h) *Zoning.* State and local codes shall apply.

[37 FR 20543, Sept. 30, 1972, as amended at 39 FR 34666, Sept. 27, 1974]

Subpart C—Health Professions Student Loans

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); secs. 740-744 of the Public Health Service Act, 77 Stat. 170-173, 90 Stat. 2266-2268, 91 Stat. 390-391 (42 U.S.C. 294m-q).

SOURCE: 44 FR 29055, May 18, 1979, unless otherwise noted.

§ 57.201 Applicability.

The regulations of this subpart apply to the federal capital contributions made by the Secretary to public or other nonprofit health professions schools for the establishment of health professions student loan funds and to loans made to students by schools from these funds.

§ 57.202 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Date upon which a student ceases to be a full-time student" means the first day of the month which is nearest to the date upon which an individual ceases to be a full-time student as defined in this section.

"Federal capital loan" means a loan made by the Secretary to a school under section 744(a) of the Act, as in effect prior to October 1, 1977, the proceeds of which are to be returned to the Secretary.

"Full-time student" means a student who is enrolled in a health professions school and pursuing a course of study which is a full-time academic workload, as determined by the school, leading to a degree specified in section 741(b) of the Act.

"Health professions school" or "school" means a public or private nonprofit school of medicine, school of dentistry, school of osteopathy, school of pharmacy, school of podiatry, school of optometry, and school of veterinary medicine as defined in section 701(4) of the Act.

"Health professions student loan" means the amount of money advanced to a student by a school from a health professions student loan fund under a properly executed promissory note.

"Institutional capital contribution" means the money provided by a school, in an amount not less than one-ninth of the federal capital contribution, and deposited in a health professions student loan fund.

"National of the United States" means (1) a citizen of the United States, or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States.

"School year" means the traditional approximately 9-month September to June annual session. For the purpose of computing school year equivalents for students who, during a 12-month period, attend for a longer period than the traditional school year, the school year will be considered to be 9 months in length.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, The Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 57.203 Application by school.

(a) Each school seeking a federal capital contribution must submit an application at the time and in the form and manner than the Secretary may require.[1] The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the regulations of this subpart, and the terms and conditions of the award.

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[1] Applications and instructions are available from the Division of Manpower Training Support, Bureau of Health Manpower, Center Building, 3700 East-West Highway, Hyattsville, Maryland 20782.

(b) Each application will be reviewed to determine eligibility and the reasonableness of the amount of Federal support requested. The Secretary may require the applicant to submit additional data for this purpose.

(c) An application will not be approved unless an agreement between the Secretary and the applicant school for a federal capital contribution under section 740 of the Act is reached.

§ 57.204 Payment of Federal capital contributions.

(a) *Annual payment.* The Secretary will make payments to each school with which he or she has entered into an agreement under the Act at a time determined by him or her. If the total of the amounts requested for any fiscal year by all schools for federal capital contributions exceeds the amount of Federal funds determined by the Secretary at the time of payment to be available for this purpose, the payment to each school will be reduced to whichever is smaller:

(1) The amount requested in the application, or

(2) An amount which bears the same ratio to the total amount of Federal funds determined by the Secretary at the time of payment to be available for that fiscal year for the Health Professions Student Loan Program as the number of full-time students estimated by the Secretary to be enrolled in that school bears to the estimated total number of full-time students in all participating schools during that year. Amounts remaining after these payments are made will be distributed in accordance with this paragraph among schools whose applications requested more than the amount paid to them, but with whatever adjustments that may be necessary to prevent the total paid to any school from exceeding the total requested by it.

(b) *Method of payment.* The payment of federal capital contributions to a school will be paid in a manner that avoids unnecessary accumulations of money in any health professions student loan fund.

§ 57.205 Health professions student loan funds.

(a) *Funds established with federal capital contributions.* Any fund established by a school with federal capital contributions will be deposited and carried in a special account of the school. At all times the fund must contain monies representing the institutional capital contribution. This fund is to be used by the school only for

(1) Health professions student loans to full-time students;

(2) Capital distribution as provided in section 743 of the Act or as agreed to by the school and the Secretary,

(3) Costs of litigation and, to the extent specifically approved by the Secretary, other collection costs that exceed the usual expenses incurred in the collection of health professions student loans.

§ 57.206 Eligibility and selection of health professions student loan applicants.

(a) *Determination of eligibility.* (1) Applicants are eligible for consideration for a health professions student loan if they are:

(i) Nationals of the United States, permanent residents of the Trust Territory of the Pacific Islands or the Northern Mariana Islands or lawful permanent residents of the United States, Puerto Rico, the Virgin Islands or Guam;

(ii) Enrolled, or accepted for enrollment in the school as full-time students;

(iii) In need of the amount of the loan to pursue a full-time course of study at the school; and

(iv) Of exceptional financial need in the case of students of medicine or osteopathy who will graduate after June 30, 1979. A student will be considered to demonstrate exceptional financial need if the school determines that his or her resources, as described in § 57.206(b)(1), do not exceed the lesser of $5,000 or one-half of the costs of attendance at the school. Summer earnings, educational loans, veterans (G.I.) benefits and earnings during the school year will not be considered as resources in determining whether an applicant meets the eligibility criteria for exceptional financial need.

(2) The school must provide written notification to each applicant of the provisions of section 741(f) of the Act under which the Secretary may repay all or part of a loan.

(b) *Selection of applicants.* The school will select qualified applicants, including medical and osteopathic applicants, and determine the amount of student loans by considering:

(1) The financial resources available to the student by using one of the national need analysis systems or any other procedure approved by the Commissioner of Education and published under 45 CFR 144.13 in combination with other information which the school has regarding the student's financial status. The school must take into account, regardless of the tax status of the student, the expected contribution from parents, spouse, self or other family members; and

(2) The costs reasonably necessary for the student's attendance at the school, including any special needs and obligations which directly affect the student's ability to attend the school on a full-time basis. The school must document the criteria used for determining these costs.

(c) *Selection of medical and osteopathic student applicants.* In addition to the factors in § 57.206(b), the school must select medical and osteopathic students graduating after June 30, 1979, based on the order of greatest need, taking into consideration the other resources available to the student through the school. For purposes of establishing priority for selecting medical and osteopathic student applicants to receive health professions student loans, summer earnings, educational loans, veterans (G.I.) benefits, and earnings during the school year will be considered as financial resources.

[44 FR 32698, June 7, 1979]

§ 57.207 Maximum amount of health professions student loans.

The total of the health professions student loans made from the fund to any student for a school year may not exceed $2,500 and the cost of tuition. The maximum amount loaned during a 12-month period to any student enrolled in a school which provides a course of study longer than the 9-month school year may be proportionately increased.

§ 57.208 Health professions student loan promissory note.

(a) *Promissory note form.* Each health professions student loan must be evidenced by a promissory note approved by the Secretary.

(1) Each promissory note must state that the loan will bear interest on the unpaid balance computed only for periods during which repayment of the loan is required, at the rate of 9 percent per year.

(2) A copy of each executed note must be supplied by the school to the student borrower.

(b) *Security.* A school may require security or endorsement only if the borrower is a minor and if, under the applicable State law, the note signed by him or her would not create a binding obligation.

[44 FR 29055, May 18, 1979, as amended at 47 FR 38325, Aug. 31, 1982]

§ 57.209 Payment of health professions student loans.

(a) Health professions student loans from any fund may be paid to or on behalf of student borrowers in installments considered appropriate by the school except that a school may not pay to or on behalf of any borrower more during any given installment period (e.g., semester, term, or quarter) than the school determines the student needs for that period.

(b) No payment may be made from a fund to or on behalf of any student borrower if at the time of the payment the borrower is not a full-time student.

§ 57.210 Repayment and collection of health professions student loans.

(a) Each health professions student loan, including accrued interests, will be repayable in equal or graduated periodic installments in amounts calculated on the basis of a 10-year repayment period. Except as otherwise provided in this paragraph, repayment of a loan must begin one year after the student ceases to be a full-time student.

(1) If a borrower reenters the same or another school as a full-time student within the 1-year period, the date upon which interest will accrue and the repayment period will begin will be determined by the date on which the student last ceases to be a full-time student at that school.

(2) The following periods will be excluded from the 10-year repayment period: (i) all periods for up to a total of 3 years of active duty performed by the borrower as a member of the Army, Navy, Air Force, Marine Corps, Coast Guard, National Oceanic and Atmospheric Administration Corps or the U.S. Public Health Service Corps; (ii) all periods for up to a total of 3 years of service as a volunteer under the Peace Corps Act; and (iii) all periods of advanced professional training except that with respect to health professions student loans made prior to November 18, 1971 but after June 30, 1969, these periods of advanced training may not exceed a total of 5 years.[2]

(3) Each student borrower may, subject to the provisions of paragraph (b)(3) of this section, choose the repayment schedule which he or she prefers from those in use by the school, but a student borrower may at his or her option and without penalty, prepay all or part of the principal and accrued interest at any time.

(b) *Collection of health professions student loans.* (1) Each school at which a fund is established must exercise due diligence in the collection of all health professions student loans due the fund. The school must use the collection practices which are generally accepted among institutions of higher education and which are at least as extensive and effective as those used in the collection of other student loan accounts due the school.

(2) With respect to any health professions student loan made after June 30, 1969, the school may fix a charge for failure of the borrower to pay all or any part of an installment when it is due, and in the case of a borrower who is entitled to a deferment under section 741(c) of the Act, or cancellation or repayment under section 741(f) of the Act for any failure to file timely and satisfactory evidence of the entitlement. The amount of the charge may not exceed $1 for the first month or part of a month by which the installment or evidence is late and $2 for each succeeding month or part of a month. The school may elect to add the amount of this charge to the principal amount of the loan as of the day after the day on which the installment or evidence was due, or to make the amount of the charge payable to the school no later than the due date of the next installment following receipt of the notice of the charge by the borrower.

(3) With respect to any health professions student loan made after June 30, 1969, the school may require the borrower to make payments of at least $15 per month on all outstanding health professions student loans during the repayment period.

§ 57.211 Cancellation of health professions students loans for disability or death.

(a) *Permanent and total disability.* The Secretary will cancel a student borrower's indebtedness in accordance with section 741(d) of the Act if the borrower is found to be permanently and totally disabled on recommendation of the school and as supported by whatever medical certification the Secretary may require. A borrower is totally and permanently disabled if he or she is unable to engage in any substantial gainful activity because of a medically determinable impairment, which the Secretary expects to continue for a long time or to result in death.

(b) *Death.* The Secretary will cancel a student borrower's indebtedness in accordance with section 741(d) of the Act upon the death of the borrower. The school to which the borrower was indebted must secure a certification of death or whatever official proof is conclusive under State law.

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[2] Individuals who received health professions student loans prior to July 1, 1969, remain subject to the repayment provisions of 42 CFR 57.214(a)(2) (1976) as adopted on February 7, 1974. These provisions can be found at 39 FR 4773 (Feb. 7, 1974) and a copy can be obtained by writing the Divisions of Manpower Training Support, Bureau of Health Manpower, Center Building, 3700 East-west Highway, Hyattsville, Maryland. 20782.

§ 57.212 Repayment or cancellation of loans for practice in a health manpower shortage area.

(a) *Practicing in a health manpower shortage area.* A person who:

(1) Has obtained a degree as specified in section 741(f)(1)(A) of the Act;

(2) Has obtained one or more health professions student loans or, under a written loan agreement entered before October 12, 1976, any other loans necessary for costs (including tuition, books, fees, equipment, living and other expenses which the Secretary determines were necessary) of attending a health professions school; and

(3) Enters into an agreement to practice his or her profession for at least 2 consecutive years in a health manpower shortage area designated under section 332 of the Act, is entitled to have a portion of these loans repaid by the Secretary in accordance with paragraph (b) below. Prior to entering an agreement for repayment of loans, other than health professions student loans, the Secretary will require an individual to provide evidence satisfactory to the Secretary of the existence and reasonableness of the education loans, including a copy of the written loan agreement establishing the loan, and a notarized statement that the copy is a true copy of the loan agreement.

(b) *Repayment.* Loan repayment will be made to persons who meet the conditions set forth in paragraph (a) as follows:

(1) Upon completion by the borrower of the first year of practice as specified in the agreement, the Secretary will pay 30 percent of the principal of, and the interest on, each loan which was unpaid as of the date the borrower began his or her practice.

(2) Upon completion by the borrower of the second year of practice the Secretary will pay another 30 percent of the principal of, and the interest on, each loan which was unpaid as of the date the borrower began his or her practice.

(3) Upon completion by the borrower of a third year of practice, the Secretary will pay another 25 percent of the principal of, and interest on, each loan which was unpaid as of the date the borrower began his or her practice except that, the amount of loan repayments that may be made on behalf of a borrower in any year under paragraph (a) of this section may not exceed $10,000, and the total amount of payment which can be made under this section with respect to any loan may not exceed $50,000.

(c) *National Health Service Corps (NHSC) Scholarship recipients.* A recipient of an NHSC Scholarship under 42 CFR Part 62 may not enter into an agreement with the Secretary under this section until either (1) the participant has completed the NHSC Scholarship service obligation; (2) the Secretary has recovered from the participant an amount determined under 42 CFR 62.10, or (3) any service or payment obligation has been waived under 42 CFR 62.12. An NHSC Scholarship is not an educational loan for purposes of an agreement under this section.

§ 57.213 Continuation of provisions for cancellation of loans made prior to November 18, 1971.

Individuals who received health professions student loans as students of medicine, osteopathy, dentistry or optometry prior to November 18, 1971, may still receive cancellation of these loans for practicing in a shortage area or for practicing in a rural shortage area characterized by low family income. The regulations set forth in 42 CFR 57.216(b) (1976), as adopted on February 7, 1974 remain applicable to cancellation on this basis. The provisions can be found at 39 FR 4774 (February 7, 1974) and a copy can be obtained by writing to the Division of Manpower Training Support, Bureau of Health Manpower, Center Building, 3700 East-West Highway, Hyattsville, Maryland 20782.

§ 57.214 Repayment of loans made after November 17, 1971, for failure to complete a program of study.

In the event that the Secretary undertakes to repay educational loans under section 741(*1*) of the Act, he or she will use the following criteria to make a determination as to each applicant's eligibility:

(a) An applicant will be considered to have failed to complete the course of study leading to the first professional degree for which an eligible education loan was made upon certification by a health professions school that the individual ceased to be enrolled in the school subsequent to November 17, 1971;

(b) An applicant will be considered to be in exceptionally needy circumstances if, upon comparison of the income and other financial resources of the applicant with his or her expenses and financial obligations, the Secretary determines that repayment of the loan would constitute a serious economic burden on the applicant. In making this determination, the Secretary will take into consideration the applicant's net financial assets, his or her potential earning capacity, and the relationship of the income available to the applicant to the low-income levels published annually by the Secretary under paragraph (c) of this section;

(c) An applicant will be considered to be from a low-income family if the applicant comes from a family with an annual income below a level based on low-income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and adjusted by the Secretary for use in this program, and the family has no substantial net financial assets. Income levels as adjusted will be published annually by the Secretary in the FEDERAL REGISTER.

(d) An applicant will be considered to be from a disadvantaged family if the individual comes from a family in which the annual income minus unusual expenses which contribute to the economic burdens borne by the family does not exceed the low-income levels published by the Secretary under paragraph (c) of this section and the family has no substantial net financial assets;

(e) An applicant will be considered as not having resumed his or her health professions studies within two years following the date the individual ceased to be a student upon a certification so stating from the applicant; and

(f) An applicant will be considered as not reasonably expected to resume his or her health professions studies within two years following the date upon which he or she terminated these studies, based upon consideration of the reasons for the applicant's failure to complete these studies, taking into account such factors as academic, medical, or financial difficulties.

The Secretary will only repay education loans made subsequent to November 17, 1971.

§ 57.215 Records, reports, inspection, and audit.

(a) Each Federal capital contribution and Federal capital loan is subject to the condition that the school must maintain those records and file with the Secretary those reports relating to the operation of its health professions student loan fund that the Secretary may find necessary to carry out the purposes of the Act and these regulations. The school also must comply with the requirements of 45 CFR Part 74 and section 705 of the Act concerning recordkeeping, audit, and inspection.

(b) The following student records must be retained by the school for five years after an individual student ceases to be a full-time student:

(1) Approved student applications for health professions student loans;

(2) Documentation of the financial need of applicants;

(3) Reasons for approval or disapproval of applications and;

(4) Other records as the Secretary may prescribe. Individual student records may be destroyed at the end of the five-year period, except that in all cases where questions have arisen as a result of a Federal audit, the records must be retained until resolution of all the questions.

§ 57.216 Nondiscrimination.

(a) Participating schools are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations apply:

(1) Section 704 of the Act (42 U.S.C. 292d) and its implementing regulation, 45 CFR Part 83 (prohibiting discrimination on the basis of sex in the admission of individuals to training programs).

(2) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its implementing regulation, 45 CFR Part 80 (prohibiting discrimination in Federally assisted programs on the grounds of race, color, or national origin).

(3) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) and its implementing regulation, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in Federally assisted education programs).

(4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and its implementing regulation, 45 CFR Part 84 (prohibiting discrimination in Federally assisted programs on the basis of handicap).

(b) The recipient may not discriminate on the basis of religion in the admission of individuals to its training programs.

§ 57.217 Additional conditions.

The Secretary may with respect to any agreement entered into with any school under § 57.205, impose additional conditions prior to or at the time of any award when in his or her judgment these conditions are necessary to assure or protect the advancement of the purposes of the agreement, the interest of the public health, or the conservation of funds awarded.

§ 57.218 Noncompliance.

Wherever the Secretary finds that a participating school has failed to comply with the applicable provisions of the Act or the regulations of this subpart, he or she may, on reasonable notice to the school, withhold further payment of Federal capital contributions, and take such other action, including the termination of any agreement, as he or she finds necessary to enforce the Act and regulations. In this case no further expenditures shall be made from the health professions student loan fund or funds involved until the Secretary determines that there is no longer any failure of compliance.

Subpart D—Nursing Student Loans

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216).

SOURCE: 39 FR 16473, May 9, 1974, unless otherwise noted.

§ 57.301 Applicability.

The regulations in this subpart are applicable to Federal Capital Contributions and Federal Capital Loans made by the Secretary to public or other nonprofit schools of nursing under sections 822 and 827 of the Public Health Service Act and to loans made to students by such schools pursuant thereto.

§ 57.302 Definitions.

All terms not defined herein shall have the same meaning as given them under title VIII of the Act. As used in this subpart, the following terms shall have the following meanings:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health and Human Services, and any other officer or employee to whom the authority involved has been delegated.

(c) "School" means a public or other nonprofit school of nursing as defined in section 843 of the Act.

(d) "Nursing Student Loan Fund or Funds" means a Fund established at a school pursuant to part B of title VIII of the Act, either with Federal Capital Contributions together with Institutional Capital Contributions, or with Federal Capital Loans. Where a school received monies from both sources of payment, reference is made to Funds.

(e) "Federal Capital Contribution" means the capital portion allotted by the Secretary to a school for deposit in a Nursing Student Loan Fund pursuant to section 824 of the Act.

(f) "Institutional Capital Contribution" means the money provided by a school, in an amount not less than one-ninth of the Federal Capital Contribution, and deposited in a Nursing Student Loan Fund.

(g) "Federal Capital Loan" means a loan made by the Secretary to a school pursuant to section 827(a) of the Act: the proceeds of which are to be deposited in a Nursing Student Loan Fund.

(h) "Nursing student loan" means the amount of money advanced to a student by a school from a Nursing Student Loan Fund as defined in paragraph (d) of this section, under a properly executed promissory note.

(i) "Educational loan" means a nursing student loan as defined in paragraph (h) of this section or the amount of money provided to a student under any other bona fide loan which the Secretary determines was reasonably necessary for meeting the student's costs of attending a school of nursing, taking into account the tuition, fees, books, equipment, living expenses, and such other expenses as the Secretary determines were reasonably necessary to enable an individual to attend such school.

(j) "Full-time student" means a student who is enrolled in a school and pursuing a course of study which constitutes a full-time academic workload, as determined by the school, leading to a diploma in nursing, an associate degree in nursing or an equivalent degree, a baccalaureate degree in nursing or an equivalent degree, or a graduate degree in nursing.

(k) "Half-time student" means a student who is enrolled in a school and pursuing a course of study which constitutes at least one-half of a full-time academic workload but less than a full-time academic workload, as determined by the school, leading to a diploma in nursing, an associate degree in nursing, a baccalaureate degree in nursing or an equivalent degree, or a graduate degree in nursing.

(l) "Good standing" means the eligibility of a student to continue in attendance at the school where he is enrolled as a student in accordance with the school's standards and practices.

(m) "Date upon which a student ceases to be a full-time or half-time student" means the first day of the month which is nearest to the date upon which he ceases to be a full-time or half-time student as defined in paragraphs (j) and (k) of this section, respectively.

(n) "Academic year" means the traditional, approximately 9-month September to June annual session. For the purpose of computing academic year equivalents for students who, during a 12-month period, attend for a longer period than the traditional academic year, the academic year will be considered to be of 9 months' duration.

(o) "Fiscal year" means the Federal fiscal year commencing on the first day of July and ending on the 30th day of June.

(p) "Permanently and totally disabled" means the inability to engage in any substantial gainful activity because of medically determinable impairment, which impairment is expected to continue for a long and indefinite period of time, or to result in death.

(q) "Uniformed service" means the Army, Navy, Air Force, Marine Corps, Coast Guard, National Ocean Survey, and the U.S. Public Health Service.

(r) "National of the United States" means (1) a citizen of the United States or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States (8 U.S.C. 1101(a)(22)).

(s) "State health authority" means the Director of the agency responsible for administering or supervising the administration of the State plan for health services under section 314(d) of the Act.

(t) "Registered nurse" means an individual who has been licensed by a State Board of Nursing to practice professional nursing pursuant to State licensing laws requiring as a minimum one of the degrees or diplomas specified in paragraph (j) of this section.

§ 57.303 Eligibility of schools.

To be eligible for a Federal Capital Contribution or a Federal Capital Loan under this subpart, the applicant shall meet the applicable requirements of sections 822(a) and 827(a) of the Act.

§ 57.304 Application by school.

(a) Each school desiring a Federal Capital Contribution or a Federal Capital Loan under Title VIII of the Act shall submit an application in such form and at such time as the Secretary may require.[1] The application shall be executed by an official authorized to act for the applicant school and to assume on behalf of the applicant school the obligations imposed by the terms and conditions of any Federal Capital Contribution or Federal Capital Loan, including the regulations of this subpart.

(b) Each application shall be reviewed to determine institutional eligibility and the reasonableness of the amount requested. When necessary to these ends, the Secretary may require the submission of additional data.

§ 57.305 Agreements for Federal Capital Contributions and Federal Capital Loans.

(a) *Federal Capital Contribution agreements.* No application for a Federal Capital Contribution shall be approved unless there is in effect an Agreement between the Secretary and the applicant school for Federal Capital Contributions pursuant to section 822 of the Act.

(b) *Federal Capital Loan agreements.* No application for a Federal Capital Loan shall be approved unless there is in effect an Agreement between the Secretary and the applicant school for Federal Capital Loans containing the terms required by section 827(b) of the Act and such additional terms and conditions, consistent with the applicable provisions of section 822 of the Act, as the Secretary deems appropriate.

§ 57.306 Allotment and payment of Federal Capital Contributions and Federal Capital Loans.

(a) *Annual allotment.* At a time determined by him, the Secretary shall make allotments to each school with which he has entered into an agreement pursuant to § 57.305. The allotment to each school, whether in the form of Federal Capital Contributions or Federal Capital Loans or a combination of both, shall be an amount which bears the same ratio to the total amount of Federal funds determined by the Secretary at the time of such allotment to be available for such fiscal year for the Nursing Student Loan Program as the number of full-time students in such schools bears to the estimated total number of full-time students in all such schools in all the States during such year.

(b) *Supplementary allotment from revolving fund only.* From funds which become available during any fiscal year for payment to schools from the revolving fund established by section 827(a) of the Act after the allotments pursuant to paragraph (a) of this section for such fiscal year have been made, the Secretary may, in his discretion and at such time as he shall determine, make supplementary allotments to schools with which he has Federal Capital Loan Agreements and who request funds for such fiscal year in excess of the amounts allotted to them pursuant to paragraph (a) of this section. If the total need for supplementary funds exceeds the amount determined by the Secretary to be available for supplementary allotments, the supplementary allotment to each school shall be reduced to whichever of the following is the smaller:

(1) The supplementary amount requested or

(2) An amount which bears the same ratio to the amount determined by the Secretary to be available for supplementary allotment as the number of full-time students estimated by the Secretary to be enrolled in such school bears to the estimated total number of full-time students enrolled for such year in all schools which request supplementary allotments. Any amounts remaining after such supplementary allotment may be allotted among schools in such manner as the Secretary determines will best carry out the purposes of the Act.

(c) *Payment.* The allotment of Federal Capital Contributions and/or Federal Capital Loans to a school shall be paid in such amounts, at such times, and in such installments as will not result in unnecessary accumulation of money in any Nursing Student Loan Fund.

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[1] Applications and instructions are available from the Regional Health Manpower Director at the Regional Office of the Department of Health and Human Services for the region in which the applicant is located.

§ 57.307 Federal Capital Loan Promissory note.

Each Federal Capital Loan shall be made subject to the terms of a promissory note which shall be executed by an authorized official on behalf of the borrowing school. Each such note shall include such terms with respect to the payment of interest and the repayment of principal as are consistent with the provisions of section 827 of the Act, and shall include such other terms as the Secretary finds reasonably necessary to protect the financial interests of the United States and to promote the purposes of the Act.

§ 57.308 Nursing Student Loan Funds.

(a) *Funds established with Federal Capital Contributions.* Any fund established by a school with Federal Capital Contributions shall be deposited and carried in a special account of such school. There shall be in such fund at all times monies representing the Institutional Capital Contribution, equal to at least one-ninth of the amount of the balance of the Federal Capital Contributions in such fund.

(1) Except for funds transferred as provided for in paragraph (a)(2) of this section, such fund shall be used by such school only for (i) nursing student loans to students; (ii) capital distribution as provided in section 826 of the Act or as agreed to by the school and the Secretary; and (iii) costs of litigation and, to the extent specifically approved by the Secretary, other collection costs that are in excess of the usual expenses incurred in the collection of nursing student loans.

(2) Not to exceed 20 percent of the amount paid to any such school from the appropriation for any fiscal year ending after June 30, 1969, for Federal Capital Contributions may be transferred to the sums available to the school for scholarship awards under section 860 of the Act, to be used for the same purpose as such sums; *Provided, however,* That where the Secretary finds in a particular case that a school has demonstrated an unusual need for scholarship funds, he may approve the transfer of any amount in excess of 20 percent of the amount so paid. In the case of any transfer pursuant to this paragraph, the proportionate amount of the Institutional Capital Contribution (i.e., one-ninth of the amount so transferred) may be withdrawn by the school from such fund.

(b) *Funds established with Federal Capital Loans.* Any fund established by a school with Federal Capital Loans shall be deposited and carried in a special account of such school, and shall be used by such school only for

(1) Nursing student loans to students;

(2) Repayments of principal and interest on Federal Capital Loans; and

(3) Costs of litigation and, to the extent specifically approved by the Secretary, other collection costs that are in excess of the usual expenses incurred in the collection of nursing student loans.

§ 57.309 Nondiscrimination.

(a) No eligible applicant shall be denied a nursing student loan on the grounds of sex or creed.

(b) Attention is called to the requirements of section 845 of the Act and 45 CFR Part 83 which together provide that the Secretary may not enter into a contract under title VIII of the Act with any entity unless he receives satisfactory assurances that the entity will not discriminate on the basis of sex in the admission of individuals to its training programs.

(c) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252; 42 U.S.C. 2000d et seq.), which provides that no person in the United States shall, on the grounds of race, color or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which is applicable to Federal Capital Contributions and Federal Capital Loans made under Title VIII of the Act, has been issued by the Secretary with the approval of the President (45 CFR Part 80).

(d) Attention is called to the requirements of Title IX of the Education Amendments of 1972 and in particular to section 901 of such Act which provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any education program or activity receiving Federal financial assistance.

§ 57.310 Eligibility and selection of nursing student loan recipients.

(a) *Eligibility.* Nursing student loans from any fund may be made only to students who are:

(1) Nationals of the United States or who are in a State for other than temporary purposes and intend to become permanent residents of a State;

(2) Enrolled, or accepted for enrollment, in the school as full-time or half-time students, as defined in § 57.302 (j) and (k) respectively;

(3) In need of the amount of the loan to pursue the course of study at the school; and

(4) Capable, in the opinion of the school, of maintaining good standing in such course of study.

(b) *Selection of nursing student loan recipients and determination of need.* It shall be the responsibility of the school to select qualified applicants and to make reasonable determinations of need.

(1) In selecting nursing student loan recipients, the school shall give preference to licensed practical nurses.

(2) In determining whether a student is in need of a nursing student loan to pursue a full-time or half-time course of study at the school, the school shall take into consideration:

(i) The financial resources available to the student, and

(ii) The costs reasonably necessary for the student's attendance at the school, including any special needs and obligations which directly affect the student's financial ability to attend the school on a full-time or half-time basis.

(c) *Records of approval or disapproval.* The records of the school shall indicate the basis for approval or disapproval of all or any part of each student application for a nursing student loan.

§ 57.311 Maximum amount of nursing student loan.

(a) *Maximum per academic year.* Effective on November 18, 1971, the total of the nursing student loans made from a Fund or Funds to any student for an academic year may not exceed $2,500. The maximum amount loaned during a 12-month period to any student enrolled in a school which provides a course of study longer than the 9-month academic year may be proportionately increased.

(b) *Aggregate maximum.* Effective on November 18, 1971, the aggregate of nursing student loans for all years from a Fund or Funds may not exceed $10,000 in the case of any student.

§ 57.312 Evidence of student indebtedness—promissory note; security.

(a) *Evidence of indebtedness—promissory note.* Each nursing student loan to a student from any Fund or Funds shall be evidenced by a promissory note executed by the student borrower, in such form as shall be approved by the Secretary.

(1) Any substantive deviations from the promissory note form so approved shall be made only pursuant to approval by the Secretary prior to the making of any nursing student loan evidenced thereby, except that a school which elects to require security or endorsement in cases permitted under paragraph (b) of this section may include a provision reflecting such election without prior approval.

(2) Each promissory note executed subsequent to June 30, 1969, shall include a provision stating that the nursing student loan evidenced thereby shall bear interest, on the unpaid balance of such loan, computed only for periods during which repayment of the loan is required, at the rate of 3 percent per year.

(3) A copy of each executed note shall be supplied by the school to the student maker thereof.

(b) *Security.* Neither security nor endorsement shall be required except that if the borrower is a minor and if under the applicable State law the note executed by him would not create a binding obligation, then the school is permitted to require security or endorsement.

§ 57.313 Payment of nursing student loans.

(a) Nursing student loans from any Fund or Funds shall be paid to or on behalf of student borrowers in such installments as are deemed appropriate by the school, except that no school shall pay to or on behalf of any borrower more during any given installment period (e.g., semester, term, or quarter) than the school determines that he needs for such period.

(b) No payment shall be made from any Fund to or on behalf of any student borrower if at the time of such payment such borrower is not a full-time or half-time student as defined in § 57.302 (j) and (k), respectively.

§ 57.314 Repayment and collection of nursing student loans.

(a) *Repayment of nursing student loans.* Subject to the provisions of this paragraph, any nursing student loan including interest accrued thereon, shall be repayable in equal or graduated periodic installments in amounts calculated on the basis of a 10-year repayment period. Except as otherwise provided in this paragraph, repayment of any nursing student loan made after June 30, 1969 shall begin 9 months after the student ceases to be a full-time or half-time student: *Provided, however,* That in the case of students who received nursing student loans subsequent to June 30, 1969, but prior to November 18, 1971, repayment shall begin 9 months after the student ceases to be a full-time student.

(1) When a borrower, within such 9-month period, reenters the same or another school of nursing as a full-time or half-time student, the date upon which interest accrual and the repayment period begin shall be related to and determined by the date on which he last ceases to be a full-time or half-time student at any such school: *Provided, however,* That in the case of students who received loans subsequent to June 30, 1969, but prior to November 18, 1971, this provision will apply only if the student reentered such school as a full-time student.

(2) The following periods shall be excluded from the 10-year repayment period:

(i) All periods of up to a total of 3 years of active duty performed by the borrower as a member of a uniformed service;

(ii) All periods of up to a total of 3 years of service as a volunteer under the Peace Corps Act; and

(iii) All periods up to a total of 5 years during which the borrower is pursuing a full-time course of study at a school leading to a baccalaureate degree in nursing or an equivalent degree, or to a graduate degree in nursing, or is otherwise pursuing advanced professional training in nursing. For purposes of this paragraph, "otherwise pursuing advanced professional training in nursing" shall include only full-time training, beyond the first diploma or degree in nursing received by the particular borrower, of at least one academic year which will advance the borrower's knowledge of and strengthen his skills in the provision of nursing services.

(3) With respect to nursing student loans made before July 1, 1969, all periods specified in paragraph (a)(2) of this section after June 30, 1968, may be excluded from such repayment period where so agreed by the school which made such loan and the borrower: *Provided, however,*

(i) That in no such case may the total of the periods excluded from the repayment period pursuant to paragraphs (a)(2)(i) or (a)(2)(ii) of this section and the period between the date on which the borrower ceases to be a full-time student and the date on which, under the terms of the promissory note evidencing such loan, the repayment period is to begin, exceed 3 years and 9 months; and

(ii) That in any such case all periods during which the borrower is pursuing a full-time course of study at a school leading to a baccalaureate degree in nursing or an equivalent degree, or to a graduate degree in nursing, shall be excluded from the repayment period, without limitation; and

(iii) That in no such case may the total of the periods excluded from the repayment period because the borrower is otherwise pursuing advanced professional training in nursing and the period between the date on which the borrower ceases to be a full-time student and the date on which, under the terms of the promissory note evidencing such loan, the repayment period is to begin, exceed 5 years and 9 months.

(4) Each student borrower may (subject to the provisions of paragraph (b)(3) of this section) choose the repayment schedule which he prefers from those in use by the school and approved by the Secretary, but a student borrower may, at his option and without penalty, prepay all or part of the principal and accrued interest at any time.

(b) *Collection of nursing student loans.* (1) Each school at which a Fund is established shall exercise due diligence in the collection of all nursing student loans due the Fund. The school shall use such collection practices as are generally accepted among institutions of higher education and which are at least as extensive and effective as those used in the collection of other student loan accounts due the school.

(2) With respect to any nursing student loan made after June 30, 1969, the school may assess a charge for failure of the borrower to pay all or part of an installment when it is due, and, in the case of a borrower who is entitled to deferment benefits under section 823(b)(2) of the Act or concellation benefits under section 823(b)(3) of the Act, for any failure to file timely and satisfactory evidence of such entitlement. The amount of such charge may not exceed $1.00 for the first month or part of a month by which such installment or evidence is late and $2.00 for each such month or part of a month thereafter. The school may elect to add the amount of such charge to the principal amount of the nursing student loan as of the first day after the day on which such installment or evidence was due or to make the amount of the charge payable to the school not later than the due date of the next installment after receipt by the borrower of notice of the assessment of the charge.

(3) With respect to any nursing student loan made after June 30, 1969, the school may provide that during the repayment period of such loan, payments of principal and interest by the borrower with respect to all the outstanding nursing student loans made to him from any Nursing Student Loan Fund shall be at a rate equal to not less than $15.00 per month.

§ 57.315 Cancellation of nursing student loans for disability and death.

(a) *Permanent and total disability.* Determinations as to whether or not a student borrower is entitled to cancellation of indebtedness in accordance with section 823(b)(4) of the Act on the basis of permanent and total disability shall be made by the Secretary on the recommendation of the school to whose fund the borrower is indebted, supported by such medical certifications as the Secretary may require relating to the borrower's disability.

(b) *Death.* The determination as to whether or not a student borrower is entitled to cancellation of indebtedness in accordance with section 823(b)(4) of the Act because of the death of the borrower shall be made by the school to which the borrower is indebted on the basis of a certification of death or such other official proof as is conclusive under State law.

§ 57.316 Loan cancellation or repayment for service.

(a) *Cancellation for full-time employment as a registered nurse.* (1) Any person who obtained one or more nursing student loans from a loan Fund or Funds established under Title VIII of the Act and who engages in full-time employment as a registered nurse (including teaching in any of the fields of nurse training or service as an administrator, supervisor, or consultant in any of the fields of nursing) in any public or nonprofit private agency, institution, or organization (including neighborhood health centers) shall be entitled upon compliance with the statute, the regulations of this subpart and instructions issued pursuant thereto, to have a portion of such nursing student loans canceled as follows: Fifteen percent of the total amount of such loans (plus accrued interest thereon) which is unpaid on the first day of such service, for each of the first, second, and third year of such service, and 20 percent of the total of such amount (plus accrued interest thereon) for each complete fourth and fifth year of such service thereafter, up to 85 percent of the total of such loans, plus accrued interest thereon: *Provided, however,* That with respect to nursing student loans made prior to November 18, 1971 a borrower shall only be entitled to cancellation of an amount not to exceed 50 per centum of any such loan plus accrued interest thereon) at the rate of 10 per centum of the amount of such loan (plus accrued interest thereon), which was unpaid on the first day of such service, for each complete year of such service.

(2) The determination of whether a borrower is entitled to have any portion of his nursing student loan canceled for such full-time employment as a registered nurse shall be made by the institution to whose fund such loan is payable, upon receipt and evaluation of an application for cancellation from such borrower.

(b) *Repayment and cancellation for service in shortage area.* (1) Subject to the provisions of section 823(h) of the Act and of this paragraph, any person who has obtained the degree or diploma specified in § 57.302(j) and who has obtained an educational loan as defined in § 57.302(i) of this subpart and who enters into an agreement with the Secretary to serve as a full-time registered nurse for a period of at least two consecutive years in an area in a State determined by the Secretary, after consultation with the State health authority, to have a shortage of and need for nurses, is entitled to have the principal, and interest on, such loans repaid by the Secretary as follows:

(i) Upon completion by the borrower of the first year of service as specified in the agreement, the Secretary shall pay 30 percent of the principal of, and the interest on, each such loan which is unpaid as of the date the borrower began service.

(ii) Upon completion by the borrower of the second year of such service, the Secretary shall pay another 30 percent of the principal of, and the interest on, each such loan which was unpaid as of the date the borrower began such service.

(iii) Upon completion by the borrower of the third year of such service, the Secretary shall pay another 25 percent of the principal of, and interest on, each such loan which was unpaid as of the date the borrower began such service.

(2) Notwithstanding the requirement in paragraph (b)(1) of this section of completion of such service, the Secretary shall on or before the due date thereof, pay any loan or loan installment which may fall due within the period of service for which the borrower is eligible to receive such payments. Such payments will be made contingent upon a declaration by the borrower, at such times and in such manner as the Secretary may prescribe, that the borrower is then engaged in service eligible for such payments and will continue to be so engaged for the period required (in the absence of this paragraph) to entitle the borrower to have such payments made, except that no more than 85 percent of the principal of any such loan shall be paid by the Secretary pursuant to this paragraph.

(3) A borrower who fails to complete two years of service pursuant to the agreement entered into with the Secretary shall be liable to reimburse the Secretary for any payments made pursuant to such agreement.

(4) A borrower who fails to complete a third year of service shall be liable to reimburse the Secretary for any payments made pursuant to paragraph (b)(2) of this section in consideration of such service.

(5) In accordance with section 823(h) of the Act, an area in a State shall be determined by the Secretary, after consultation with the State health authority, to have a shortage of and need for nurses, based upon consideration of, among other pertinent factors:

(i) The latest reliable statistical data available to him regarding the number of registered nurses in an area and the population to be served by such nurses;

(ii) The availability of health services to the residents of the area;

(iii) Particular local health problems; and

(iv) Designation of an area under section 329(b) of the Act as one with a critical health manpower shortage.

A listing of such areas in which service as a registered nurse would qualify a borrower for repayment under paragraph (b)(1) of this section will be promulgated periodically by the Secretary and published in the FEDERAL REGISTER together with an explanation of the methodology used in determining such areas.

(6) Notwithstanding the above, any person who obtained one or more nursing student loans prior to November 18, 1971, and who engages in full-time employment as a registered nurse in a public or other nonprofit hospital in an area which has been determined by the Secretary pursuant to this paragraph to have a substantial shortage of nurses at such hospitals shall be entitled, upon compliance with the applicable statute, regulations, and instructions, to have a portion of such loans canceled as follows: Fifteen per centum of the total of such loans (plus accrued interest thereon) which is unpaid on the first day of such service, for each year of such service beginning after August 16, 1968, up to 100 percent of the total of such loans, plus accrued interest thereon.

(i) An area shall be determined to have a substantial shortage of nurses if the number of registered nurse hours of service per patient day in the public or other nonprofit hospital serving such area is lower than the median number of registered nurse hours of service per patient day for all public or other non-profit hospitals of its category in all States. For purposes of this paragraph, all public or other nonprofit hospitals in all States shall be grouped by the Secretary according to the following categories:

(A) Short-term general and allied special hospitals,

(B) Psychiatric hospitals,

(C) Tuberculosis hospitals,

(D) Chronic and convalescent hospitals, and

(E) All other hospitals.

(ii) For purposes of this paragraph, a year of service in a public or other nonprofit hospital means any 12-month period of continuous service

(A) After the date the person begins service in such hospital if the area primarily served by the hospital is at that time designated as an area in which there is a substantial shortage of nurses, or

(B) After the date as of which the area is designated an area with a substantial shortage of nurses if the area was so designated subsequent to the date that such person began service in the hospital: *Provided*, That, when an area's designation is changed, after a borrower would otherwise be eligible for cancellation of a portion of his loan by serving in the hospital in such area, so that such area no longer has a substantial shortage of nurses, such change in designation shall not affect the eligibility of such borrower to have a portion of his loan canceled for any year in which he continues to serve as a nurse in the hospital in such area.

(iii) The determination of whether a borrower is entitled to have a portion of his loan canceled in accordance with this paragraph shall be made by the institution to whose fund such loan is payable, upon receipt and evaluation of an application for cancellation from such borrower.

(iv) All determinations of the Secretary pursuant to this paragraph shall be made on the basis of the latest reliable statistical data available to him.

(v) Hospitals in which employment will qualify borrowers for cancellation under the provisions of this paragraph shall be identified in a list promulgated periodically by the Secretary in the FEDERAL REGISTER.

(7) Nothing in paragraph (b)(6) of this section or paragraph (a) of this section shall be construed to prevent any person from entering into an agreement with the Secretary pursuant to section 823(h) of the Act.

[39 FR 16473, May 9, 1974; 39 FR 18093, May 23, 1974]

§ 57.317 Repayment of loans made subsequent to November 17, 1971 for failure to complete program of study.

In the event the Secretary undertakes to repay educational loans pursuant to section 830 of the Act, he shall utilize the following criteria in making his determination as to each applicant's eligibility:

(a) An applicant will be considered to have failed to complete the course of study in nursing for which an eligible educational loan was made upon certification by a school of nursing that the individual ceased to be enrolled in such school subsequent to November 17, 1971;

(b) An applicant will be considered to be in exceptionally needy circumstances if, upon comparison of the income and other financial resources of the applicant with his expenses and financial obligations, the Secretary determines that repayment of such loan would constitute a serious economic burden on the applicant. In making such determination the Secretary shall take into consideration the net financial assets of the applicant and the relationship of the income available to the applicant to the low-income levels published annually by the Secretary pursuant to paragraph (c) of this section;

(c) An applicant will be considered to be from a low-income family if the applicant comes from a family with an annual income below a level based on low-income thresholds by family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index and multiplied by a factor to be determined by the Secretary for adaptation to this program, and the family has no substantial net financial assets. Such factor and income levels as adjusted will be published annually by the Secretary in the FEDERAL REGISTER.

(d) An applicant will be considered to be from a disadvantaged family if the individual comes from a family in which the annual income minus unusual expenses which contribute to the economic burdens borne by the family does not exceed the low-income levels published by the Secretary pursuant to paragraph (c) of this section and the family has no substantial net financial assets;

(e) An applicant will be considered as not having resumed his nursing studies within two years following the date the individual ceased to be a student upon a certification so stating from the applicant; and

(f) An applicant will be considered as not reasonably expected to resume his nursing studies within two years following the date upon which he terminated such studies based upon consideration of the reasons for the applicant's failure to complete these studies, taking into account such factors as academic, medical, or financial difficulties: *Provided, however,* That the Secretary shall only repay educational loans made subsequent to November 17, 1971.

§ 57.318 Records, reports, inspection and audit.

(a) *Record and reports.* (1) Each Federal Capital Contribution and Federal Capital Loan shall be subject to the condition that the school shall maintain such records, and file with the Secretary such reports relating to the operation of the Nursing Student Loan Fund or Funds, as the Secretary may find necessary to carry out the purposes of the Act and the regulations. Where any school has both a Fund established with Federal Capital Contributions and a Fund established with Federal Capital Loans, records shall be kept separately for each Fund. All such records shall be retained until such time as agreed upon with the Secretary that there is no further need for retention and must not be destroyed regardless of completion of a Federal audit.

(2) The following individual student records not related to the operation of the Fund must be retained for five years after the individual student has ceased to be at least a half-time student:

(i) Approved or disapproved student applications for assistance;

(ii) Documentation of the financial need of applicants;

(iii) Reasons for approval or disapproval of applications, and

(iv) Such other records as the Secretary may prescribe.

Such individual student records may be destroyed at the end of such five-year period except that in all cases where questions have arisen as a result of Federal audit, such records shall be retained until resolution of all such questions.

(b) *Inspection and audit.* Any application for a Federal Capital Contribution or a Federal Capital Loan shall constitute the consent of the applicant school to inspection and fiscal audit, by the Secretary and the Comptroller General of the United States or any of their duly authorized representatives, of the fiscal and other records of the applicant school which relate to such Contribution or Loan.

§ 57.319 Additional conditions.

The Secretary may with respect to any agreement entered into with any school pursuant to § 57.305, impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the purposes of the agreement, the interest of the public health or the conservation of funds awarded.

§ 57.320 Noncompliance.

Whenever the Secretary finds that a participating school has failed in a material respect to comply with the applicable provisions of the Act or the regulations of this subpart he may, on reasonable notice to the school, withhold further payments of Federal Capital Contributions or Federal Capital Loans, and take such other action, including the termination of any agreement, as he finds appropriate to carry out the purposes of the applicable provisions of the Act and regulations. In such case no further expenditures shall be made from the Nursing Student Loan Fund or Funds involved until the Secretary determines that there is no longer any such failure of compliance.

Subpart E—Grants for Construction of Nurse Training Facilities

§ 57.409 Good cause for other use of completed facility.

If, within 20 years after completion of construction (or, in the case of interim facilities prior to the time at which teaching in such facilities is moved to a permanent facility, whichever comes first), the facility shall cease to be used for any one or more of the purposes for which it was constructed, the Secretary, in determining whether there is good cause for releasing the applicant or other owner of the facility from the obligation so to use the facility, shall take into consideration the extent to which:

(a) The facility will be devoted by the applicant or other owner to the teaching of other health personnel;

(b) There are reasonable assurances that for the remainder of such period other facilities not previously utilized for nurse training will be so utilized and are substantially the equivalent in nature and extent for such purposes.

(Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216)

[37 FR 20548, Sept. 30, 1972]

Subpart F—[Reserved]

Subpart G—Scholarship Grants to Schools of Medicine, Osteopathy, Dentistry, Optometry, Podiatry, Pharmacy, and Veterinary Medicine

AUTHORITY: Sec. 780(a), 79 Stat. 1056, as amended; 42 U.S.C. 295g(d).

SOURCE: 37 FR 13177, July 4, 1972, unless otherwise noted.

§ 57.601 Applicability.

The regulations in this subpart are applicable to the award of grants under section 780 of the Public Health Service Act which authorizes the Secretary to make grants to public or other non-profit schools of medicine, osteopathy, dentistry, optometry, podiatry, pharmacy, or veterinary medicine for scholarships to be awarded annually by such school to students thereof.

§ 57.602 Definitions.

As used in this subpart, the following terms shall have the following meanings:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health and Human Services, and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) "School" means a public or other nonprofit school of medicine, dentistry, osteopathy, optometry, podiatry, pharmacy, or veterinary medicine which provides a course of study, or a portion thereof, which leads respectively to a degree of doctor of medicine, doctor of dental surgery or an equivalent degree, doctor of osteopathy, doctor of optometry or an equivalent degree, doctor of podiatry or an equivalent degree, bachelor of science in pharmacy or an equivalent degree, or doctor of veterinary medicine or an equivalent degree, and which is accredited as provided in section 721(b)(1)(B) or section 775(b)(2) of the Act.

(d) "Scholarship or scholarship award" means the amount of money awarded to a student by a school as authorized by section 780(c) of the Act.

(e) "Scholarship grant" means a grant to a school for making scholarship awards as authorized by section 780(a) of the Act.

(f) "Full-time student" means a student who is enrolled in a school and pursuing a course of study which constitutes a full-time academic workload, as determined by the school, leading to a degree specified in paragraph (c) of this section.

(g) "Good standing" means the eligibility of a student to continue in attendance at the school where he is enrolled as a student in accordance with the school's standards and practices.

(h) "Academic year" means the traditional, approximately 9-month September to June annual session. For the purpose of computing academic year equivalents for students who, during a 12-month period, attend for a longer period than the traditional academic year, the academic year will be considered to be of 9 months' duration.

(i) "Fiscal year" means the Federal fiscal year beginning July 1 and ending on the following 30th day of June.

(j) "National of the United States" means (1) a citizen of the United States or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States (8 U.S.C. 1101(a)(22)).

§ 57.603 Eligibility of schools.

To be eligible for a scholarship grant under this subpart, the applicant school shall:

(a) Meet the applicable requirements of section 780(a) of the Act;

(b) Submit an application as required by § 57-604; and

(c) Be located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

§ 57.604 Application by school.

Each school desiring a scholarship grant under section 780 of the Act shall submit an application in such form and at such time as the Secretary may require. The application shall be executed by an official authorized to act for the applicant school and to assume on behalf of the applicant school the obligations imposed by the terms and conditions of any scholarship grant, including the regulations of this subpart.

§ 57.605 Grant award; determination of number of students.

(a) The Secretary shall award annually to each eligible school applying therefor a scholarship grant in an amount computed in accordance with section 780(b) of the Act: *Provided, That,* when the amount of funds available for any fiscal year is less than the total of the amounts so computed, the grant awarded to each participating school shall be reduced proportionately.

(b) For purposes of computing the amount of the scholarship grant to be awarded to any school for any fiscal year on the basis of one-tenth of the number of full-time students, or on the basis of the number of full-time students who are from low-income backgrounds as specified in paragraph (c) of this section, the number of full-time students of such school shall be the number which the Secretary, on the basis of information relating to the school's past and anticipated enrollment determines to be the number of such students to be enrolled in such school on October 15 of such year.

(c) For purposes of this subpart, students will be considered to be from "low-income backgrounds" if they come from families with annual incomes below levels based on low-income thresholds by family size published by the U.S. Bureau of Census, as adjusted annually for changes in the consumer price index, multiplied by a factor to be determined by the Secretary for adaptation to this program. Such factor and the income levels as adjusted will be published annually by the Secretary in the FEDERAL REGISTER.

§ 57.606 Use of funds.

(a) *Scholarship awards.* Effective July 1, 1972, except for funds transferred as provided in paragraph (b) of this section, scholarship grant funds may be obligated by the school for scholarship awards to eligible students during the 12-month period specified in the grant award document and for awarding additional scholarships to eligible students during the 12 months thereafter. Any funds not so transferred or obligated in the specified 24-month period of fund availability must be refunded to the Federal Government.

(b) *Transfer of funds.* In the case of a school which has in operation a Health Professions Student Loan Fund established with Federal Capital Contributions pursuant to section 740 of the Act, an amount not to exceed 20 per centum of the amount paid to a school from the appropriation for any fiscal year for scholarships under section 780 of the Act and this subpart, or such larger percentage thereof as the Secretary may approve for such school for such year, may be transferred to the sums available to the school for (and shall be regarded as) Federal Capital Contributions, to be used for the same purpose as such sums.

§ 57.607 Nondiscrimination.

(a) No eligible applicant shall be denied a scholarship on the grounds of sex or creed.

(b) Attention is called to the requirements of section 799A of the Act which provides that the Secretary may not make a grant, loan guarantee, or interest subsidy payment under title VII of the Act to, or for the benefit of, any school of medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, podiatry, or public health or any training center for allied health personnel unless the application contains assurances satisfactory to the Secretary that the school or training center will not discriminate on the basis of sex in the admission of individuals to its training programs.

(c) Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.), which provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which is applicable to grants made under this subpart, has been issued by the Secretary with the approval of the President (45 CFR Part 80).

§ 57.608 Eligibility and selection of scholarship recipients.

(a) *Eligibility.* Scholarships may be awarded with respect to any year only to students who are:

(1) Nationals of the United States or permanent residents of the Trust Territory of the Pacific Islands or who intend to become permanent residents of the United States, Puerto Rico, the Virgin Islands, or Guam;

(2) Enrolled and in good standing, or accepted for enrollment, in the school as full-time students; and

(3) Of exceptional financial need who need such financial assistance to

pursue a course of study at the school for such year.

(b) *Selection of scholarship recipients and determination of need.* (1) It shall be the responsibility of the school to select qualified applicants and to make reasonable determinations of need.

(2) In determining whether a student is one of exceptional financial need who needs such financial assistance to pursue a course of study at the school for such year, the school shall take into consideration:

(i) The financial resources available to the student; and

(ii) The costs reasonably necessary for the student's attendance at the school, including any special needs and obligations which directly affect the student's ability to attend the school on a full-time basis.

(c) *Records of approval or disapproval.* The records of the school shall indicate the basis for approval or disapproval of all or any part of each student application for a scholarship award.

§ 57.609 Maximum amount of scholarship award.

The total amount of the scholarship award to any student for an academic year may not exceed $3,500. The maximum amount of scholarship awarded during a 12-month period to any student enrolled in a school which provides a course of study longer than the 9-month academic year may be proportionately increased. However, in no case may the amount of scholarship award exceed the amount of the student's need as determined by the school in accordance with § 57.608.

§ 57.610 Payment of scholarship award.

(a) Scholarship awards shall be paid to students in such installments as are deemed appropriate by the school, except that no school shall pay any scholarship recipient more during any given installment period (e.g., semester, term, or quarter) than the school determines he needs for such period.

(b) No payment shall be made from any scholarship award to any student if at the time of such payment such student is not a full-time student as defined in § 57.602(f).

§ 57.611 Records, reports, inspection and audit.

(a) *Records and reports.* Each grant awarded pursuant to this subpart shall be subject to the condition that the grantee shall maintain such operational and accounting records, identifiable by grant number, and file with the Secretary such operational and fiscal reports relating to the use of grant funds, as the Secretary may find necessary to carry out the purposes of the Act and the regulations. Where applicable, such records shall include documentation regarding the determination of the number of full-time students who are from low-income backgrounds required pursuant to § 57.605(c) of these regulations. All records shall be retained for 3 years after the close of the budget period (i.e., the period of time during which the funds are available for obligation by the grantee. See § 57.606(a)). Such records may be destroyed at the end of such 3-year period if the applicant has been notified of the completion of the Federal audit by such time. If the applicant has not been so notified, such records shall be retained (1) for 5 years after the close of the budget period or (2) until the grantee is notified of the completion of the Federal audit, whichever comes first. In all cases where audit questions have arisen before the expiration of such 5-year period, records shall be retained until resolution of all such questions.

(b) *Inspection and audit.* Any application for a scholarship grant shall constitute the consent of the applicant school to inspection and fiscal audit, by persons designated by the Secretary, of the fiscal and other records of the applicant school which relate to the grant.

§ 57.612 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the grant purposes, the interest of the public health or the conservation of grant funds.

§ 57.613 Noncompliance.

Whenever the Secretary finds that a participating school has failed in a material respect to comply with section 780 of the Act or the regulations of this subpart, he may, after reasonable notice, withhold further payments, and take such other action as he finds necessary to carry out the purposes of section 780 of the Act and these regulations. In such case no further expenditures shall be made by the school from the scholarship grant until the Secretary determines there is no longer any such failure of compliance.

Subpart H—Grants for Physician Assistant Training Programs

Authority. Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 783(a)(1) of the Public Health Service Act, 90 Stat. 214 (42 U.S.C. 295g-3(a)(1).

Source: 44 FR 36178, June 21, 1979, unless otherwise noted.

§ 57.701 Applicability.

The regulations in this subpart apply to the award of grants to public or nonprofit private schools of medicine or osteopathy, and other public or nonprofit private entities under section 783(a)(1) of the Public Health Service Act (42 U.S.C. 295g-3(a)(1)) to meet the costs of projects to plan, develop, and operate or maintain programs for the training of physician assistants.

§ 57.702 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Budget period" means the interval of time into which the approved activity is divided for budgetary and reporting purposes, as specified in the grant award document.

"Council" means the National Advisory Council on Health Professions Education (established by section 702 of the Act).

"Health manpower shortage area" means an area designated under section 332 of the Act.

"Nonprofit" as applied to any entity means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

"Physician assistant" means an individual who is qualified by academic and clinical training to provide patient care services under the supervision and responsibility of a doctor of medicine or osteopathy and who meets the requirements of 42 CFR 57.802.

"Primary care" means health care which may be initiated by the patient or the provider, or both, in a variety of settings, and which consists of a broad range of personal health care services including promotion and maintenance of health, prevention of illness and disability, basic care during acute and chronic phases of illness, guidance and counseling of individuals and families, and referral to other health care providers and community resources when appropriate. In providing the services (1) the physical, emotional, social, and economic status of the patient is considered in the context of his or her cultural and environmental background, including the family and community, and (2) the patient is provided timely access to the health care system.

"Project director" means an individual designated by the grantee in the grant application and approved by the Secretary to direct the project being supported under this subpart.

"Project period" means the total time for which support for a project has been approved including any extensions of the project.

"School of medicine" or "school of osteopathy" means a school which provides training leading respectively to a degree of doctor of medicine or a degree of doctor of osteopathy, and which is accredited as provided in section 772(b) of the Act.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

"Supervised clinical practice" means supervised clinical practice as defined in 42 CFR 57.802(g).

"Program for the Training of Physician Assistants" or "Program" means a program for the training of physician assistants as defined in 42 CFR 57.801-803.

§ 57.703 Eligibility.

Any public or non-profit private school of medicine or osteopathy or public or non-profit private entity located in a State may apply for a grant under this subpart.

§ 57.704 Application.

(a) Each eligible applicant seeking a grant under this subpart must submit an application at the time and in the form that the Secretary may require.[1]

(b) The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations of this subpart.

(c) In addition to other pertinent information which the Secretary may require, an application for a grant under this subpart must contain:

(1) A detailed description of the proposed project and of the manner in which the applicant intends to conduct the project and carry out the requirements of section 783 of the Act and this subpart, in particular, the requirements of § 57.705. This must include a budget for the proposed project and a justification for the amount of grant funds requested.

(2) A copy of all laws and regulations pertaining to the practice of physician assistants in the State or States in which the applicant's supervised clinical practice will be conducted and in which the applicant will be encouraging its graduates to work.

(3) A description of the present employment of any graduates of the program, to the extent available, and a description of the methods to be used by the program in placing its graduates.

(4) Evidence that all applicable requirements of section 1513(e) of the Act have been met.

§ 57.705 Project requirements.

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) The project must conduct its program for the training of physician assistants in accordance with the requirements in 42 CFR 57.803.

(b) The program must (1) be accredited by the American Medical Association's Committee on Allied Health Education and Accreditation, or (2) have received a Letter of Support from the Joint Review Committee on Educational Programs for Physician's Assistants.

(c) The program must be operational no later than 12 months after the award of a grant under this subpart.

(d) The project must be conducted under the direction of the project director who must be employed full-time at the grantee institution(s). If the project director becomes unable to function in this capacity, the Secretary must be notified as soon as possible.

(e) The project must evaluate the supervised clinical practice conducted by the program with respect to:

(1) The variety of patient contact and care experiences afforded to participating students;

(2) The adequacy and quality of supervision provided to participating students; and

(3) The adequacy of the physical setting or settings in which the supervised clinical practice takes place.

(f)(1) The project must provide on an annual basis, upon request and in a format acceptable to the Secretary, information in the aggregate regarding student characteristics, student attrition rate and student performance.

(2) The project must provide on an annual basis, upon request and in a format acceptable to the Secretary, in-

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[1] Applications and instructions may be obtained from the Grants Management Officer, Bureau of Health Manpower, HRA, Room 4-22, 3700 East-West Highway, Center Building, Hyattsville, MD 20782.

formation in the aggregate regarding the employment of its graduates including place of employment.

(Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 783(a)(1) of the Public Health Service Act, 90 Stat. 214 (42 U.S.C. 295g-3(a)(1))

[37 FR 20543, Sept. 30, 1972, as amended at 45 FR 41420, June 19, 1980]

§ 57.706 Evaluation of applications.

(a) The Secretary, after consultation with the Council, will approve or disapprove all applications filed in accordance with § 57.704, taking into consideration:

(1) The degree to which the project plan adequately provides for meeting the requirements set forth in § 57.705 and 42 CFR 57.803;

(2) The potential effectiveness of the project in carrying out the purposes of section 783 of the Act and this subpart;

(3) The capability of the applicant to carry out the proposed project;

(4) The local, regional, and national needs the project proposes to serve, including those identified by the Health Systems Agency and/or State Health Planning and Development Agency of the State or States in which the project will encourage graduates to practice;

(5) The adequacy of the project's plan for placing graduates in health manpower shortage areas;

(6) The soundness of the fiscal plan for assuring effective use of grant funds; and

(7) The potential of the project to continue on a self-sustaining basis after the period of grant support.

(b) In determining the priority for funding of applications approved under paragraph (a) of this section, the Secretary will consider:

(1) The relative merit of the proposed project based upon the factors in paragraph (a) of this section; and

(2) The extent to which a proposed project contains any of the following elements:

(i) Conducts a program for training physician assistants to provide primary care patient services under the supervision of a doctor of medicine or osteopathy.

(ii) Conducts substantial portions of the program in a health manpower shortage area(s) or in an area health education center, funded under section 781 of the Act;

(iii) Establishes a program in a State which does not have a program; and

(iv) Conducts a program in conjunction with primary care physician education in a manner which shares educational resources and encourages the use of physician assistants by physicians.

§ 57.707 Grant award.

(a) *General.* (1) Within the limits of funds available for this purpose, the Secretary may award grants to those applicants whose projects will, in his or her judgment best promote the purposes of section 783 of the Act as determined in accordance with § 57.706.

(2) All grant awards will be in writing and will state the amount of funds granted and the period for which grant funds will be available for obligation by the grantee.

(3) Neither the approval of any project nor any grant award obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion of an approved project. For continuation support, grantees must make separate application at the time and in the form as the Secretary may require.

(b) The Secretary will determine the amount of any award on the basis of his or her estimate of the sum necessary for the cost (including both direct and indirect costs) of the project.

(c) The Secretary may make a grant award for an additional budget period for any previously approved project if, on the basis of progress and accounting records, the Secretary finds that the project's activities during the current budget period justify continued support of the project for an additional budget period.

§ 57.708 Grant payments.

The Secretary will from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement.

§57.709 Purposes for which grant funds must be spent.

(a) Grant funds must be spent solely for carrying out the approved project under section 783 of the Act, these regulations, and the terms and conditions of the grant award.

(b) Grant funds may not be spent for sectarian instruction or any other religious purpose.

(c) Any unobligated funds remaining in the grant account at the close of a budget period may be carried forward and will be available for obligation during subsequent budget periods of the project period. The amount of any subsequent award will take into consideration the amount remaining in the grant account. At the end of the last budget period, any unobligated funds remaining in the grant account must be refunded to the Federal Government.

§57.710 Nondiscrimination.

(a) In addition to the terms and conditions of these regulations, the following laws and regulations apply to grantees:

(1) Section 704 of the Act (42 U.S.C. 292d) and its implementing regulations, 45 CFR Part 83 (prohibiting discrimination on the basis of sex in the admission of individuals to training programs).

(2) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its implementing regulations, 45 CFR Part 80 (prohibiting discrimination in Federally-assisted programs on the grounds of race, color, or national origin).

(3) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) and its implementing regulations, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in Federally-assisted education programs).

(4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and its implementing regulations, 45 CFR Part 84 (prohibiting discrimination in Federally-assisted programs on the basis of handicap).

(b) The grantee may not discriminate on the basis of religion in the admission of individuals to its training programs.

§57.711 Grantee accountability.

(a) *Accounting for grant award payments.* The grantee must record all payments made by the Secretary in accounting records separate from the records of all other funds, including funds derived from other grant awards. The grantee must account for the sum total of all amounts paid by making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart.

(b) *Grant closeout.* (1) *Date of final accounting.* A grantee must submit with respect to each grant under this subpart, a full account, in accordance with this subsection, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* The grantee must pay to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for under paragraphs (a) and (b) of this section; and

(ii) Any other amounts due in accordance with 45 CFR Part 74 and the terms and conditions of the grant award. This total sum constitutes a debt owed by the grantee to the Federal Government and is recoverable from the grantee or its successors or assignees by setoff or other lawful action.

§57.712 Records, audit, and inspection.

Each entity which receives a grant under this subpart must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act, concerning recordkeeping, audit, and inspection.

§57.713 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, apply to all grants awarded under this subpart.

§57.714 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when, in his or her judgment, these conditions are necessary to assure or protect advancement of the grant, the interest of the public health, or the conservation of grant funds.

Subpart I—Programs for the Training of Physician Assistants

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 701(7)(B), 90 Stat. 2247 (42 U.S.C. 292a(7)(B)).

SOURCE: 44 FR 36177, June 21, 1979, unless otherwise noted.

§ 57.801 Purpose and scope.

(a) Section 701(7)(B) of the Public Health Service Act (42 U.S.C. 292a(7)(B)) requires the Secretary to develop regulations for programs for the training of physician assistants. The purpose of this subpart is to comply with this requirement.

(b) The regulations in this subpart apply to all programs for the training of physician assistants supported under Title VII of the Public Health Service Act.

§ 57.802 Definitions.

For purpose of this subpart:

"Academic year" means the approximately 9-12 month period of time during which the program is in session.

"Full-time student" means a student who is enrolled in a program and pursuing a course of study which constitutes a full-time academic workload, as determined by the program, and which leads to a degree, diploma, or certificate of completion.

"Health manpower shortage area" means an area designated under section 322 of the Public Health Service Act.

"Medical director" means the individual responsible for providing competent medical direction of the program.

"Physician assistant" means an individual who is qualified by academic and clinical training to provide patient care services under the supervision and responsibility of a doctor of medicine or osteopathy. At a minimum, the physician assistant is competent to:

(1) Do the initial and follow-up evaluation of patients of various age groups in any setting to elicit a detailed and accurate history, perform an appropriate physical examination, and record and present pertinent data, including interpretive recommendations, in a manner meaningful to the physician;

(2) Perform or assist in the performance of routine laboratory and related studies as appropriate for a specific practice setting, such as blood studies, urinalyses, and electrocardiographic tracings;

(3) Perform routine therapeutic procedures such as injections, immunizations, and the assessment, suturing, and care of wounds;

(4) Instruct and counsel patients regarding physical and mental health, including matters such as nutrition, illness, treatment, normal growth and development, and age, sex, or lifestyle risk factors;

(5) Perform the following functions in a hospital setting: patient work-ups, making patient rounds, recording patient progress notes, accurately and appropriately transcribing or executing standing orders and other specific orders at the direction of the supervising physician, and compiling and recording detailed progress reports and narrative case summaries;

(6) Deliver or assist in the delivery of services, including the review and monitoring of treatment and therapy plans, to patients requiring initial or continuing care in settings other than a hospital, such as the home, nursing homes, and extended care facilities;

(7) Evaluate and treat life-threatening emergency situations;

(8) Interact with those community health services and other community resources which will facilitate the patient's care and continuity of care.

"Supervised clinical practice" means direct participation in patient care by observation, examination, and performance of procedures as are appropriate for the assigned role of the student for the purposes of instruction under the guidance and responsibility of a physician who holds a full and unrestricted license in the State in which the supervised clinical practice is located.

§ 57.803 Requirements.

A program for the training of physician assistants must:

(a)(1) Be accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(2) Have received a Letter of Support from the Joint Review Committee on Educational Programs for Physician's Assistants for its plans for a program for the training of physician assistants;

(b) Have a medical director who is licensed to practice medicine or osteopathy in the State in which the program is located (or any State if the program is conducted by a Federal health facility) and who is experienced in the delivery of the type of health care services for which the program provides training;

(c) Have an enrollment of not less than eight full-time students in each class;

(d) Be a minimum of one academic year in length;

(e) Consist of supervised clinical practice and at least four months (in the aggregate) of classroom instruction;

(f) Develop and use methods designed to encourage graduates of the program to work in health manpower shortage areas, such as periods of supervised clinical practice in those areas;

(g) Develop and use methods for placing graduates in positions for which they have been trained, including methods for placing graduates in positions in health manpower shortage areas.

(h) Develop and use a method for evaluating the effectiveness of the program in training physician assistants, including:

(1) Evaluation by faculty and students of the program in relation to its objectives;

(2) Evaluation of student performance in classroom instruction and supervised clinical practice; and

(3) Evaluation of the number of graduates employed and the characteristics of their employment, such as geographical location, setting, and functions performed; and

(4) Award a degree, diploma, or certificate of completion to individuals who have successfully completed the program.

Subpart J—Scholarship Grants to Schools of Nursing

Authority: Sec. 860(d), 82 Stat. 786, as amended; 42 U.S.C. 298c(d).

Source: 37 FR 12724, June 28, 1972, unless otherwise noted.

§ 57.901 Applicability.

The regulations in this subpart are applicable to the award of grants to public or other nonprofit schools of nursing under section 860 of the Public Health Service Act (42 U.S.C. 298c) for scholarships to be awarded annually by such school to students thereof.

§ 57.902 Definitions.

As used in this subpart, the following terms shall have the following meanings:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

(c) "School" means a public or other nonprofit school of nursing as defined in section 843 of the Act.

(d) "Scholarship or scholarship award" means the amount of money awarded to a student by a school as authorized by section 860(c) of the Act.

(e) "Scholarship grant" means a grant to a school for making scholarship awards as authorized by section 860(a) of the Act.

(f) "Full-time student" means a student who is enrolled in a school and pursuing a course of study which constitutes a full-time academic workload, as determined by the school, leading to a diploma in nursing, an associate degree in nursing, a baccalaureate degree in nursing or an equivalent degree, or a graduate degree in nursing.

(g) "Half-time student" means a student who is enrolled in a school and pursuing a course of study which constitutes at least one-half of a full-time academic workload, but less than a full-time academic workload, as determined by the school, leading to a diploma in nursing, an associate degree in nursing, a baccalaureate degree in nursing or an equivalent degree, or a graduate degree in nursing.

(h) "Good standing" means the eligibility of a student to continue in attendance at the school where he is enrolled as a student in accordance with the school's standards and practices.

(i) "Academic year" means the traditional, approximately 9-month September to June annual session. For the purpose of computing academic year equivalents for students who, during a 12-month period, attend for a longer period than the traditional academic year, the academic year will be considered to be of 9 months' duration.

(j) "Fiscal year" means the Federal fiscal year beginning July 1 and ending on the following 30th day of June.

(k) "National of the United States" means (1) a citizen of the United States or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States (8 U.S.C. 1101(a)(22)).

(l) "State" means a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

§ 57.903 Eligibility of schools.

To be eligible for a scholarship grant under this subpart, the applicant school shall:

(a) Meet the applicable requirements of section 860(a) of the Act;

(b) Submit an application as required by § 57.904; and

(c) Be located in a State.

§ 57.904 Application by school.

Each school desiring a scholarship grant under the Act shall submit an application in such form and at such time as the Secretary may require. The application shall be executed by an official authorized to act for the applicant school and to assume on behalf of the applicant school the obligations imposed by the terms and conditions of any scholarship grant, including the regulations of this subpart.

§ 57.905 Grant award; determination of number of students.

(a) The Secretary shall award annually to each eligible school applying therefor a scholarship grant in an amount computed in accordance with section 860(b) of the Act: *Provided*, That, when the amount of funds available for any fiscal year is less than the total of the amounts so computed the grant awarded to each participating school shall be reduced proportionately.

(b) For purposes of computing the amount of the scholarship grant to be awarded to any school for any fiscal year, the number of full-time students of such school shall be the number which the Secretary, on the basis of information relating to the school's past and anticipated enrollment, determines to be the number of such students to be enrolled in such school on October 15 of such year.

§ 57.906 Use of funds.

(a) *Scholarship awards.* Effective July 1, 1972, except for funds transferred as provided in paragraph (b) of this section, scholarship grant funds may be obligated by the school for scholarship awards to eligible students during the 12-month period specified in the grant award document and for awarding additional scholarships to eligible students during the 12 months thereafter. Any funds not so transferred or obligated in the specified 24-month period of fund availability must be refunded to the Federal Government.

(b) *Transfer of funds.* In the case of a school which has in operation a Nursing Student Loan Funds established with Federal Capital Contributions pursuant to section 822 of the Act, an amount not to exceed 20 per centum of the amount paid to a school from the appropriation for any fiscal year for scholarships under section 860 of the Act and this subpart, or such larger percentage thereof as the Secretary may approve for such school for such year, may be transferred to the sums available to the school for (and shall be regarded as) Federal Capital Contributions, to be used for the same purpose as such sums.

§ 57.907 Nondiscrimination.

(a) No eligible applicant shall be denied a scholarship on the grounds of sex or creed.

(b) Attention is called to the requirements of section 845 of the Act, which provides that the Secretary may not make a grant, loan guarantee, or interest subsidy payment under title VIII of the Act to, or for the benefit of, any school of nursing unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary that the school will not discriminate on the basis of sex in the admission of individuals to its training programs.

(c) Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) which provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which is applicable to grants made under this subpart, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR Part 80).

§ 57.908 Eligibility and selection of scholarship recipients.

(a) *Eligibility.* Scholarships may be awarded with respect to any year only to students who are:

(1) Nationals of the United States or permanent residents of the Trust Territory of the Pacific Islands or who are in the United States, Puerto Rico, the Virgin Islands, or Guam for other than temporary purposes and intend to become permanent residents thereof.

(2) Enrolled and in good standing, or accepted for enrollment in the school as full-time or half-time students; and

(3) Of exceptional financial need who need such financial assistance to pursue a course of study at the school for such year.

(b) *Selection of scholarship recipients and determination of need.* It shall be the responsibility of the school to select qualified applicants and to make reasonable determination of need.

(1) In determining whether a student is one of exceptional financial need who needs such financial assistance to pursue a course of study at the school for such year, the school shall take into consideration:

(i) The financial resources available to the student; and

(ii) The costs reasonably necessary for the student's attendance at the school, including any special needs and obligations which directly affect the student's financial ability to attend the school.

(2) In making scholarship awards to students of exceptional financial need as determined pursuant to paragraph (b)(1) of this section, a school may give priority to those students whose backgrounds are characterized by educational, cultural, or economic deprivation.

(c) *Records of approval or disapproval.* The records of the school shall indicate the basis for approval or disapproval of all or any part of each student application for a scholarship award.

§ 57.909 Maximum amount of scholarship award.

The total amount of the scholarship award to any student for an academic year may not exceed $2,000. The maximum amount of scholarship awarded during a 12-month period to any student enrolled in a school which provides a course of study longer than the 9-month academic year may be proportionately increased. However, in no case may the amount of scholarship award exceed the amount of the student's need as determined by the school in accordance with § 57.908.

§ 57.910 Payment of scholarship award.

(a) Scholarship awards shall be paid to students in such installments as are deemed appropriate by the school, except that no school shall pay any scholarship recipient more during any given installment period (e.g., semester, term, or quarter) than the school determines he needs for such period.

(b) No payment shall be made from any scholarship award to any student if at the time of such payment such student is not a full-time or half-time student as defined in § 57.902 (f) and (g), respectively.

§ 57.911 Records, reports, inspection and audit.

(a) *Records and reports.* Each grant awarded pursuant to this subpart shall be subject to the condition that the grantee shall maintain such operational and accounting records, identifiable by grant number, and file with the Secretary such operational and fiscal reports relating to the use of grant funds, as the Secretary may find necessary to carry out the purposes of Part D of title VIII of the Act and the regulations. All records shall be retained for 3 years after the close of the budget period (i.e., the period of time during which the funds are available for obligation by the grantee. See § 57.906(a)). Such records may be destroyed at the end of such 3-year period if the applicant has been notified of the completion of the Federal audit by such time. If the applicant has not been so notified, such records shall be retained (1) for 5 years after the close of the budget period, or (2) until the grantee is notified of the completion of the Federal audit, whichever comes first. In all cases where audit questions have arisen before the expiration of such 5-year period, records shall be retained until resolution of all such questions.

(b) *Inspection and audit.* Any application for a scholarship grant shall constitute the consent of the applicant school to inspection and fiscal audit, by persons designated by the Secretary, of the fiscal and other records of the applicant school which relate to the grant.

§ 57.912 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the grant purposes, the interest of the public health or the conservation of grant funds.

§ 57.913 Noncompliance.

Whenever the Secretary finds that a participating school has failed in a material respect to comply with the applicable provision of title VIII of the Act or the regulations of this subpart, he may, after reasonable notice, withhold further payments, and take such other action as he finds necessary to carry out the purposes of the act and regulations. In such case no further expenditures shall be made by the school from the scholarship grant until the Secretary determines that there is no longer any such failure of compliance.

Subpart K—Grants to Schools of Nursing for the Support of Their Educational Programs

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 810, 89 Stat. 356 (42 U.S.C. 296e).

SOURCE: 44 FR 25136, Apr. 27, 1979, unless otherwise noted.

§ 57.1001 Applicability.

The regulations of this subpart apply to the award of annual grants under section 810 of the Public Health Service Act (42 U.S.C. 296e) to schools of nursing for the support of their education programs.

§ 57.1002 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means a State, the Commonwealth of Puerto Rico, the District of Columbia, the Canal Zone, Guam, American Samoa, the Virgin Islands, or the Trust Territory of the Pacific Islands.

"Council" means the National Advisory Council on Nurse Training established by section 851(a) of the Act.

"School" or "school of nursing" means a collegiate, associate degree, or diploma school of nursing which is accredited as provided in section 853(6) of the Act.

"Collegiate school of nursing" means a department, division, or other administrative unit in a college or university which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to the degree of bachelor of arts, bachelor of science, bachelor of nursing, or to an equivalent degree, or to a graduate degree in nursing, and including advanced training related to this type of educational program provided by the school, but only if the program or unit, college, or university is accredited.

"Associate degree school of nursing" means a department, division, or other administrative unit in a junior college, community college, college, or university which provides primarily or exclusively a two-year program of education in professional nursing and allied subjects leading to an associate degree in nursing or to an equivalent degree, but only if the program, or unit, college, or university is accredited.

"Diploma school of nursing" means a school affiliated with a hospital or university, or an independent school, which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to a diploma or to equivalent indicia that the program has been satisfactorily completed, but only if the program, affiliated school, hospital, university, or independent school is accredited.

"New school" means a school which, at the time of filing an application for a grant under this subpart, has not graduated a class because of an insufficient period of operation.

"Full-time student" means a student pursuing a full-time course of study, as determined by the school, in an accredited program in a school of nursing leading to a diploma or degree specified in this section.

"Construction" means (1) the construction of new buildings and the acquisition or expansion of existing buildings (including related costs, such as architects' fees, acquisition of land, off-site improvements, and the initial equipping of such buildings); and (2) the remodeling, alteration, and repair of existing buildings.

"Program for the training of nurse practitioners" means an educational program for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) which meets guidelines prescribed by the Secretary under section 822(a)(2)(B) of the Act and which has as its objective the education of nurses (including pediatric and geriatric nurses) who will, upon completion of their studies in this program, be qualified to effectively provide primary health care, including primary health care in homes and in ambulatory care facilities, long-term care facilities, and other health care institutions.

"Nonprofit" as applied to any school means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"Fiscal year" means the Federal fiscal year as defined in 31 U.S.C. 1020(a).

§ 57.1003 Eligibility.

(a) To be eligible for a grant under this subpart the applicant shall:

(1) Be a public or nonprofit school of nursing; and

(2) Be located in a State.

(b) A new school of nursing may apply for a grant under this subpart in the fiscal year preceding the fiscal year in which it will admit its first class. For purposes of this section, the first class in a new collegiate school of nursing is (1) the second-year class in a three-year school, or (2) the third-year class in a four-year school.

§ 57.1004 Application.

(a) Each eligible school desiring a grant under this subpart shall submit an application in the form and at the time which the Secretary may prescribe.[1]

(b) The application shall be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations of this subpart.

(c) In addition to other information and assurances which the Secretary may require, an approvable application shall contain:

(1) A reasonable assurance satisfactory to the Secretary that the first-year enrollment of full-time students in the school year beginning in the fiscal year in which the grant applied for is to be made will not be less than the first-year enrollment in the school in the preceding school year. This assurance shall be in addition to any assurance given under section 802(b)(2)(D) of the Act with respect to a construction grant application, where applicable.

(2) A reasonable assurance that the school will expend in carrying out its function as a school of nursing, during the school year for which the grant is sought, an amount of funds (other than funds for construction) from non-Federal sources which is at least as great as the average amount of funds expended by the school for this purpose (excluding expenditures of a nonrecurring nature) in the three school years immediately preceding the school year for which the grant is sought. The determination of the average amount of non-Federal funds expended by a new school during this three-year period shall be the average for the three preceding school years in which expenditures were actually made in carrying out the functions of the school.

(3) Either (i) A reasonable assurance satisfactory to the Secretary that for the school year beginning in the fiscal year in which the grant is to be made, and for each school year thereafter beginning in a fiscal year in which a grant is made, the first-year enrollment of full-time students in the school will exceed the number of these students enrolled in the school year beginning during the fiscal year ending June 30, 1975, by

(A) 10 per centum of this number if it was not more than 100; or

(B) 5 per centum of this number, or 10 students, whichever is greater, if it was more than 100; or

(ii) A reasonable assurance satisfactory to the Secretary that the school will carry out, in accordance with a plan contained in or accompanying its application and approved by the Secretary, at least two of the following programs in the school year beginning in the fiscal year in which the grant applied for is to be made and in each school year thereafter beginning in a fiscal year in which the grant is made:

(A) In the case of a collegiate school of nursing, a program for the training of nurse practitioners as defined in § 57.1002.

(B) A program under which students enrolled in a school of nursing will receive a significant portion of their clinical training in community health centers, long-term care facilities, and ambulatory care facilities geographically remote from the main site of the teaching facilities of the school.

(C) a program for the continuing education of nurses which meets needs identified by appropriate State, regional, or local health or educational entities (including health systems agencies).

(D) A program to identify, recruit, enroll, retain, and graduate individuals from disadvantaged backgrounds (as determined by the school in accordance with criteria prescribed in this paragraph) under which program at least 10 per centum of each year's entering class or 10 students, whichever is greater, is comprised of these individuals. For purposes of this paragraph, the school may only consider an individual to be from a disadvantaged background if the individual:

(*1*) Comes from an environment that has inhibited the individual from obtaining the knowledge, skills, and abilities required to enroll in and graduate from a school of nursing; or

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[1] Applications and instructions may be obtained from the Division of Nursing, Bureau of Health Manpower, Health Resources Administration, Department of Health and Human Services, Center Building, Room 3-50, 3700 East-West Highway, Hyattsville, Md. 20782.

(2) Comes from a family with an annual income below a level based on low-income thresholds by family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and multiplied by a factor to be determined by the Secretary for adaptation to this program. The Secretary periodically will publish in the FEDERAL REGISTER the income levels as adjusted.

(4) In the case of an application from a new school of nursing which applies for a grant under this subpart in the fiscal year preceding the fiscal year in which it will admit its first class:

(i) Evidence satisfactory to the Secretary that where required by State law or regulation the school has received the approval of the State Board of Nursing for the State in which the school is located to enroll students in the school in the fiscal year after the fiscal year in which the grant is sought.

(ii) An estimate of the number of full-time students to be enrolled in the school in the fiscal year after the fiscal year in which the grant is made and information and assurances supporting this estimate.

§ 57.1005 Determination of number of students.

(a) For purposes of this subpart, the number of full-time students enrolled in a school, the number of full-time first-year students enrolled in a school, or the number of full-time students enrolled in a particular year-class in a school, as the case may be, for any year shall be the number of these students enrolled or to be enrolled, as the case may be, in the school on October 15 of the fiscal year for which the grant is made; however, schools which admit first-year classes in courses of study leading to a diploma or degree specified in § 57.1002 at times other than early fall may request the Secretary's approval of another official counting date for purposes of determining first-year enrollment.

(b) The classification of a full-time student as a first-year student or as a student in a particular year-class in a school shall be in accordance with the policies of the particular school, except that any student who is required to repeat one or more first-year courses after having been enrolled as a full-time student during a previous school year shall not be considered a first-year student for purposes of the enrollement requirement of section 810(c)(1)(A) of the Act and § 57.1004(c)(1) or for purposes of section 810(c)(2)(A) of the Act and § 57.1004(c)(3)(i), where applicable.

(c) For purposes of making a grant under section 810(e) of the Act to a new school of nursing which applies for a grant in the fiscal year preceding the fiscal year in which it will admit its first class, the number of full-time students enrolled in the school or in a particular year-class in the school shall be the number which the Secretary, on the basis of the information and assurances provided by the school under § 57.1004(c)(4)(ii), determines to be the number of full-time students which the school will enroll in the fiscal year after the fiscal year in which the grant is to be made. With respect to a new associate degree school of nursing, the number of full-time students enrolled in the first year of the school shall be the number of full-time students enrolled in the first year of the program of education leading to an associate degree in nursing or to an equivalent degree.

§ 57.1006 Grant award.

(a) The Secretary, after consultation with the Council, shall award a capitation grant to each applicant whose application is found to meet the applicable requirements of section 810 of the Act and the regulations of this subpart.

(b) The amount of each capitation grant shall be an amount computed in accordance with the formula set forth in section 810(a) of the Act. If the amount of funds appropriated for any fiscal year is less than the total of the amounts so computed for each school of nursing with an approved application, the grant awarded to each school shall be reduced proportionately in accordance with section 810(b) of the Act.

§ 57.1007 Grant payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement.

§ 57.1008 Expenditure of grant funds.

(a) Capitation grant funds may be obligated by the school at any time before the end of a 24-month period specified in the grant award document for any purpose related to the educational program of the school, except as provided in paragraph (b) of this section. Any funds not so obligated shall be refunded to the Federal Government.

(b) Capitation funds may not be expended for the following purposes:

(1) Construction, except that grant funds may be used for alterations and renovations;

(2) Student assistance; and

(3) Sectarian instruction or any religious purpose.

§ 57.1009 Nondiscrimination.

Recipients of grants under this subpart are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations are applicable:

(a) Section 855 of the Act (42 U.S.C. 298b-2) and its implementing regulation, 45 CFR Part 83 (prohibiting discrimination on the basis of sex in the admission of individuals to training programs).

(b) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its imlementing regulation, 45 CFR Part 80 (prohibiting discrimination in Federally assisted programs on the ground of race, color, or national origin).

(c) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) and its implementing regulation, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in Federally assisted education programs).

(d) Section 504 of the Rehabilitation Act of 1973, (29 U.S.C. 794) and its implementing regulation, 45 CFR Part 84 (prohibiting discrimination in Federally assisted programs on the basis of handicap).

§ 57.1010 Grantee accountability.

(a) Accounting for grant funds shall be in accordance with institutional accounting practices, based on generally accepted accounting principles, consistently applied regardless of the source of funds. The grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures meeting the requirements of this subpart.

(b) The total sum of: (1) Any amount not accounted for under paragraph (a) of this section, and (2) any other amounts due under Subparts F, M, and O of 45 CFR Part 74 shall be payable to the Federal Government as final settlement with respect to each grant under this subpart. This total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assigns by setoff or other lawful action.

§ 57.1011 Records and reports.

Each grant awarded under this subpart shall be subject to the condition that the grantee shall maintain financial records, identifiable by grant number, and file with the Secretary financial reports relating to the use of grant funds which the Secretary may find necessary to carry out the purposes of section 810 of the Act and the regulations of this subpart.

§ 57.1012 Inspection and audit.

Any application for a grant under this subpart shall constitute the consent of the applicant to inspections of the facilities, equipment, and other resources of the applicant at reasonable times by the Secretary and the Comptroller General of the United States or any of their duly authorized representatives. In addition, the acceptance of any grant award under this subpart shall constitute the consent of the grantee to inspections and fiscal audits by these persons of the supported activity and of progress and fiscal records relating to the use of grant funds.

§ 57.1013 Applicability of 45 CFR Part 74.

The relevant provisions of the following subparts of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants awarded under this subpart:

SUBPART

A—General.
B—Cash depositories.
C—Bonding and insurance.
D—Retention and custodial requirements for records.
F—Grant-related income.
K—Grant payment requirements.
M—Grant closeout, suspension, and termination.
O—Property.
Q—Cost principles.

§ 57.1014 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his or her judgment these conditions are necessary to assure or protect advancement of the grant purposes, the interests of the public health, or the conservation of grant funds.

Subpart L—Grants for Residency Training in the General Practice of Dentistry

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 as amended, 63 Stat. 35 (42 U.S.C. 216); Sec. 786(b) of the Public Health Service Act, 90 Stat. 2315 (42 U.S.C. 235g-6(b)).

SOURCE: 43 FR 54931, Nov. 24, 1978, unless otherwise noted.

§ 57.1101 To what projects do these regulations apply?

These regulations apply to the award of grants under section 786(b) of the Public Health Service Act to schools of dentistry and to accredited postgraduate dental training institutions to meet the cost of projects to: (a) Plan, develop and operate an approved residency training program in the general practice of dentistry; and (b) provide financial assistance (in the form of traineeships and fellowships) to residents participating in a program who are in need of financial assistance and who plan to practice general dentistry.

§ 57.1102 Definitions.

As used in this subpart:

"Accredited postgraduate dental training institution" means a public or private nonprofit institution which operates a postgraduate dental training program that has received an accreditation classification of "accreditation eligible," "provisional approval," "conditional approval," or "approval," by the Commission on Accreditation of Dental and Dental Auxiliary Educational Programs.

"Act" means the Public Health Service Act, as amended.

"Approved residency training program" or "program" means a general practice residency program in dentistry which has received an accreditation classification of "accreditation eligible," "provisional approval," "conditional approval," or "approval" by the Commission on Accreditation of Dental and Dental Auxiliary Educational Programs.

"Budget period" means an interval of time into which the project period is divided for budgetary purposes, as specified in the grant award document.

"Nonprofit school" means a school owned or operated by one or more corporations or associations no part of the net earnings of which inures or may lawfully inure, to the benefit of any private shareholder or individual.

"Practice of general dentistry" means a practice of dentistry in which the dentist:

(1) Serves as a patient's first contact with the dental care system and provides the means of timely entry into that system;

(2) Evaluates the patient's general medical status and relates this to anticipated dental treatment;

(3) Assumes continuing responsibility for the patient's dental care and provides a comprehensive range of services which will minimize the need for patient referral;

(4) Coordinates dental treatment provided by dental specialists and by dental auxiliary personnel, including

dental hygienists, dental assistants, and expanded function dental auxiliaries, as defined in 42 CFR Part 57, Subpart HH.

"Project period" means the total time for which support for a project has been approved, including any extensions thereof.

"School of dentistry" means a public or private nonprofit school which provides training leading to a degree of doctor of dentistry or an equivalent degree and which is accredited as provided in section 772(b) of the Act.

"Secretary" means the Secretary of Health and Human Services, and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means in addition to the several States, the District of Columbia, Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 57.1103 What entities are eligible to apply for a grant?

Any school of dentistry or accredited postgraduate dental training institution located in a State may apply for a grant.

§ 57.1104 How must an entity apply for a grant?

(a) To apply for a grant, each entity must submit an application in the form and at the time that the Secretary requires.[1]

(b) The application must be signed by an individual authorized to act for the applicant and to assume, on behalf of the applicant, the obligations imposed by the terms and conditions of any award including the regulations of this subpart.

(c) In addition to other pertinent information that the Secretary may require, an application for a grant under this subpart must contain: (1) A full and adequate description of the proposed project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, in particular the requirements of § 57.1105, and (2) a budget justification for the funds requested. If the applicant requests funds for stipend support of residents the applicant must provide evidence showing that income available from other sources, including income derived from services of the residents in the program, will be insufficient to pay their salaries and that grant funds will not be used to supplant other available funds.

§ 57.1105 What requirements must a project meet?

A project supported under this subpart must meet the following requirements:

(a) The project staff must plan, develop, and/or operate an approved residency program in the general practice of dentistry.

(b) Each project must have at least two residents enrolled in the training program.

(c) If the training site provides medical care, then the medical and dental care of patients must be coordinated.

(d) If a primary care medical residency program is conducted by the applicant, then joint training experiences must be provided. For purposes of this paragraph, primary care means internal medicine, family medicine, or pediatrics.

(e) Each resident who receives stipend support must sign a statement of intent to work in the practice of general dentistry.

(f) The training program, the performance of each resident, and the quality of patient care must be evaluated.

§ 57.1106 What are the criteria for deciding which applications are to be funded?

The Secretary, after consultation with the National Advisory Council on Health Professions Education established by section 702 of the Act, will approve or disapprove applications filed in accordance with § 57.1104, taking into consideration, among other pertinent factors:

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[1] Applications and instructions may be obtained from the Grants Management Officer, Bureau of Health Manpower, Health Resources Administration, 3700 East-West Highway, Hyattsville, Md. 20782.

(a) The potential effectiveness of the proposed project in carrying out the training purposes of section 786(b) of the Act;

(b) The degree to which the proposed project adequately provides for meeting the project requirements set forth in § 57.1105;

(c) The administrative and managerial capability of the applicant to carry out the proposed project in a cost-effective manner;

(d) The qualifications of proposed staff and faculty; and

(e) The potential of the project to continue on a self-sustaining basis after the period of grant support.

§ 57.1107 How will grant awards be made?

(a) *General.* (1) Within the limit of funds available, the Secretary will award grants to those applicants whose approved projects will, in his or her judgment, best promote the purposes of section 786(b) of the Act, as determined in accordance with § 57.1106.

(2) All grant awards will be in writing and will specify the amount of funds granted and the period for which these funds will be available for obligation by the grantee. The initial period of support for any grant period for any grant under this subpart may not exceed three years.

(3) Neither the approval of any project nor the award of any grant commits or obligates the United States in any way to make additional supplemental, continuation or other awards with respect to any approved project or any portion of an approved project. For continuation support, grantees must make separate application at the time and in the form which the Secretary may prescribe.

(4) The Secretary may make a grant award for an additional budget period for any previously approved project on the basis of an application and those progress and accounting records which may be required. If the Secretary finds that the project's activities during the current budget period justify continued support for an additional budget period, and the Secretary decides to continue support, the amount of the grant award will be determined in accordance with paragraph (b) of this section.

(b) *Determination of grant amount.* The Secretary will determine the amount of any award under this subpart on the basis of his or her estimate of the sum necessary for the direct costs of the project plus an additional amount for indirect costs, if any, which the Secretary will calculate either (1) on the basis of his or her estimate of the actual indirect costs of the project, or (2) on the basis of a percentage of all, or a portion of the estimated direct costs of the project when there are reasonable assurances that the use of the percentage will not exceed the approximate actual indirect costs. This award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the Secretary has determined the amount properly expended by the grantee for provisional items. In addition, determining the amount of stipend support to be made available, the amount of any stipend must be limited to that portion of the annual amount normally paid to other residents by the applicant which the Secretary determines, on the basis of the documentation required in the application, cannot reasonably be paid from other available funds, including the incomes derived from the residents' services.

§ 57.1108 How will grant payments be made?

The Secretary will, from time to time, make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement.

§ 57.1109 Purposes for which grant funds may be spent.

(a) Any funds granted under this subpart, as well as other funds required as a condition of the grant to be used in the performance of the approved project may be expended solely for carrying out the approved project in accordance with section 786(b) of the Act, the regulations of this subpart, and the terms and conditions of the award.

(b) Any unobligated grant funds remaining in the grant account at the close of a budget period may be carried forward and be available for obligation during subsequent budget periods of the project period. The amount of a subsequent award will take into consideration the amount remaining in the grant account. At the end of the last budget period of the project period, any unobligated grant funds remaining in the grant account must be refunded to the Federal Government.

(c) Grants funds may not be used for sectarian instruction or for any other religious purpose.

§ 57.1110 What nondiscrimination requirements apply to grantees?

(a) Recipients of grants under this subpart are advised that in addition to the terms and conditions of these regulations the following laws and regulations are applicable to the administration of these grant awards:

(1) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its implementing regulation, 45 CFR Part 80 (prohibiting discrimination in Federally assisted programs on the ground of race, color or national origin);

(2) Title IX of the Educational Amendments of 1972 (20 U.S.C. 1681 *et seq.*) and its implementing regulation, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in Federally assisted education programs);

(3) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and its implementing regulation, 45 CFR Part 84 (prohibiting discrimination in Federally assisted programs on the basis of handicap);

(4) Section 704 of the Act (42 U.S.C. 292d) and its implementing regulation, 45 CFR Part 83 (prohibiting discrimination on the basis of sex in admission of individuals to training programs).

(b) The grantee may not discriminate on the basis of religion in the admission of individuals to its training programs.

§ 57.1111 How must grantees account for grant funds received?

(a) *Accounting for grant award payments.* The grantee must record all payments made by the Secretary in accounting records separate from the records of all other funds, including funds derived from other grant awards. The grantee must account for the sum total of all amounts paid by presenting or otherwise making available, evidence satisfactory to the Secretary of funds spent for costs meeting the requirements of this subpart.

(b) *Grant closeout.*

(1) *Date of final accounting.* A grantee must submit, with respect to each grant under this subpart, a full account, in accordance with this subpart, as of the date of the termination of grant support.

The secretary may require other special and periodic accounting.

(2) *Final settlement.* The grantee must pay to the Federal Government as final settlement with respect to each grant under this subpart the total sum of (i) any amount not accounted for under paragraphs (a) and (b) of this section; and (ii) any other amounts due in accordance with 45 CFR Part 74 and the terms and conditions of the grant award. This total sum constitutes a debt owed by the grantee to the Federal Government and is recoverable from the grantee or its successors or assigns by set off or other lawful action.

§ 57.1112 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, apply to all grants under this subpart.

§ 57.1113 What recordkeeping, audit, and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act, concerning recordkeeping, audit, and inspection.

§ 57.1114 What additional conditions apply to grantees?

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his or her judgment these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart M—Financial Distress Grants to Health Professions Schools

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 788(b), 90 Stat. 2319 (42 U.S.C. 295g-8(b)).

SOURCE: 45 FR 55728, Aug. 21, 1980, unless otherwise noted.

§ 57.1201 To what programs do these regulations apply?

These regulations apply to the award of grants under section 788(b) of the Public Health Service Act (42 U.S.C. 259g-8(b)) to assist schools of medicine, osteopathy, dentistry, veterinary medicine, optometry, podiatry, pharmacy, and public health in meeting their costs of operation, if they are in serious financial distress, or in meeting accreditation requirements, if they have a special need for assistance in meeting these requirements, and to carry out appropriate operational, managerial, and financial reforms.

§ 57.1202 Definitions.

"Act" means the Public Health Service Act, as amended.

"Comprehensive cost analysis study" means an in-depth review of all the significant factors and circumstances affecting costs incurred in the operation and management of the institution. The review includes, but is not limited to, personnel and property utilization and practices, cost efficiency in specific areas of operation, and the search for additional sources of revenue.

"Construction" or "cost of construction" means the construction of new buildings or the expansion or acquisition of existing buildings (including related costs such as architect's fees, acquisition of land, offsite improvements, and the initial equipping of these buildings).

"School" means a public or other nonprofit school of medicine, osteopathy, dentistry, veterinary medicine, optometry, podiatry, pharmacy, or public health as defined in section 701(4) of the Act, which is accredited according to section 772(b) of the Act.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 57.1203 Who is eligible to apply for a grant?

(a) Any school which is located in a State is eligible to apply for a grant if it is either in serious financial distress or has a special need for financial assistance in meeting accreditation requirements.

(b) For purposes of this subpart; (1) a school is in serious financial distress if it has incurred costs in excess of its ability to pay for those costs; and (2) a school has a special need for financial assistance in meeting accreditation requirements if it cannot meet its accreditation requirements within the school's revenues.

§ 57.1204 What assurances are required of an applicant?

(a) The applicant must provide assurances satisfactory to the Secretary that it will spend in carrying out its functions as a school during the fiscal year for which the grant is sought, an amount of funds (other than funds for construction) from non-Federal sources which is at least as great as the average amount of funds from non-Federal sources spent for this purpose by the school during the preceding two fiscal years. The determination of the average amount of funds from non-Federal sources spent by a new school which has been in operation for less than two years will be the amount of expenditures which were actually made in carrying out the functions of the school in the preceding year.

(b) The Secretary may, in individual cases, require additional assurances where he or she finds that additional assurances are necessary to carry out the purposes of section 788(b) of the Act.

§ 57.1205 What requirements may the Secretary impose?

The Secretary will make grants upon terms and conditions which he or she determines are reasonable and necessary, including requirements that the school:

(a) Disclose any financial information which the Secretary decides is necessary to determine the cause of the school's financial distress;

(b) Conduct a comprehensive cost analysis study, as directed by the Secretary; and

(c) Carry out operational, managerial, and financial reforms which the Secretary decides are appropriate on the basis of the comprehensive cost analysis study and other relevant information. These reforms may include increasing tuition or obtaining increased financial support from State or local governmental units.

§ 57.1206 How will applications be evaluated?

After consultation with the National Advisory Council on Health Professions Education established by section 702 of the Act, the Secretary will award grants by considering the following among other factors:

(a) The extent to which the school is either unable to meet its incurred costs or has a special need for financial assistance to met its accreditation requirements;

(b) The reasons for the school's failure to meet its costs or accreditation requirements and the alternatives available to the school to meet its costs or requirements; and

(c) The actions which the applicant has taken to alleviate the need for financial assistance to meet its costs of operation or accreditation requirements and the applicant's plan to eliminate this need in the future.

§ 57.1207 How is the amount of the award determined?

The amount of the award will be based on the Secretary's estimate of the sum necessary for the costs of the approved activity. Grant awards to meet incurred costs in excess of a school's ability to pay these costs may not exceed the actual funds necessary to meet such excess costs of the school through June 30 of the Federal fiscal year for which the grant is sought, plus an amount which the Secretary estimates is necessary to carry out appropriate operational, managerial and financial reforms.

§ 57.1208 How long does grant support last?

(a) The written notice of grant award specifies the period during which grant funds are available for obligation by the grantee. This period will not exceed one year.

(b) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

§ 57.1209 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations. Grant funds may be spent to:

(1) Pay for costs incurred for all school fiscal years through June 30 of the Federal fiscal year for which the grant is sought. These costs exclude construction (other than alterations and renovations), student aid, and other costs not allowable under § 57.1211. Costs may include the amortization of the principal portion of loans for construction, student aid, and other costs not allowable under § 57.1211, with the prior written approval of the Secretary.

(2) Meet accreditation requirements; and

(3) Carry out, under an approved plan, appropriate operational, managerial, and financial reforms.

(b) Grant funds may be paid or transferred to the school's parent organization for services provided for the operation of the school only with the prior written approval of the Secretary.

(c) Grant funds may not be used for sectarian instruction, or any other religious purpose.

§ 57.1210 What other audit and inspection requirements apply to grantees?

Each grantee must, in addition to the applicable requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act, concerning audit and inspection.

§ 57.1211 What additional Department regulations apply to grantees?

(a) Several other regulations apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50—PHS grant appeals process
45 CFR Part 16—Department grant appeals process
45 CFR Part 46—Protection of human subjects
45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance from the Department—Implements Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and procedure for hearings under Part 80
45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs
45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally assisted programs
45 CFR Part 86—Nondiscrimination on the basis of sex in Federally assisted education programs
45 CFR Part 91[1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance

(b) The provisions of 45 CFR Part 74, establishing uniform administrative procedures and cost principles apply to all awards granted under this subpart, except that, in the case of grants awarded to assist schools unable to pay for incurred costs or meet accreditation requirements, the following provisions of 45 CFR 74.172(a) are modified as listed below:

(1) Costs normally not allowed under the following sections will be allowed: Sections J.2; J.4; J.17 (a), (b), and (c); J.19; J.25; J.29; J.39; J.40; J.41(a)(2); and J.43(f).

(2) Costs normally allowed under the following section will not be allowed: Section J.9.

(3) The grantee may not charge any indirect costs to a grant under this subpart, since direct costs include those identified in section F.

§ 57.1212 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of any award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the continued viability of the school, the interest of the public health, or the conservation of grant funds.

Subpart N—Grants for Dental Team Practice Training Program

Authority: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 783(a)(3) of the Public Health Service Act, 90 Stat. 2314 (42 U.S.C. 295g.3(a)(3)).

Source: 44 FR 4473, Jan. 22, 1979, unless otherwise noted.

§ 57.1301 To what projects do these regulations apply?

The regulations in this subpart are applicable to the award of grants to public or nonprofit private schools of dentistry and other public or nonprofit private entities under section 783(a)(3) of the Public Health Service Act to meet the costs of projects to plan, develop, and operate or maintain a program to train dental students in the organization and management of a multiple auxiliary dental team (referred to as team) practice. In a team practice, dental auxiliaries are used for the purpose of improving the dentist's productivity and the efficiency of dental services provided to patients.

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[1] When issued.

§ 57.1302 Definitions.

For purposes of this subpart:

"Act" means the Public Health Service Act, as amended.

"Budget period" means the interval of time into which the project period is divided for budgetary and reporting purposes, as specified in the grant award document.

"Council" means the National Advisory Council on Health Professions Education established by section 702 of the Act.

"Dental assistant" means an individual who assists the dentist with the clinical, laboratory, or business operation of a dental practice and provides services to patients as may be delegated and supervised by the dentist in accordance with the law or regulations of the State in which the individual is employed.

"Dental auxiliary" means a dental assistant, dental hygienist, or expanded function dental auxiliary.

"Dental hygienist" means an individual who is trained and licensed to function as a member of the dental care team and provide preventive and therapeutic direct care services to patients as may be delegated and supervised by the dentist in accordance with the law or regulations of the State in which the individual is employed.

"Expanded function dental auxiliary" mean a dental assistant or dental hygienist who has received additional training in a program for the training of expanded function dental auxiliaries as defined in section 701(8)(A) of the Act, 42 U.S.C. 292a(8)(A) or in a similar training program, and is qualified to perform under the supervision of a dentist a wide range of clinical functions and direct patient care procedures in accordance with the law or regulations of the State in which the individual is employed.

"Four-handed, sit-down dentistry" means a mode of dental practice which encourages the efficient use of dental assistants and dental hygienists to assist the dentist or operating dental auxiliary in a manner that maximizes patient and operator comfort, saves time, and increases the productivity of the practice while maintaining the quality of dental care. This mode of practice includes, but is not limited to, the following:

(1) Preplanning of patient treatment;

(2) Chair positioning of patient, operator, and dental auxiliary;

(3) Use of prearranged sterilized instrument trays;

(4) Effective hand instrument exchange techniques;

(5) Standardized sequential usage of instruments;

(6) Use of water, air, and oral evacuation equipment to maintain a clear field of operation; and

(7) Preparation and delivery of restorative and other treatment materials required for the procedures.

"Project period" means that total time for which support for a project has been approved, including any extensions thereof.

"School of dentistry" means a school which provides training leading to a degree of doctor of dentistry or an equivalent degree and which is accredited as provided in section 772(b) of the Act (42 U.S.C. 295f-5).

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 57.1303 What entities are eligible to apply for a grant?

Any public or nonprofit private school of dentistry or other public or nonprofit private entity located in a State may apply for a grant under this subpart.

§ 57.1304 How must an entity apply for a grant?

(a) Each eligible applicant desiring a grant under this subpart must submit an application in the form and at the time as the Secretary may require.[2] The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the Act, the regulations of this subpart, and any additional terms and conditions of the award.

(b) In addition to other pertinent information as the Secretary may require, an application for a grant under this subpart must set forth a full description of the project; including the manner in which the applicant proposes to meet the requirements of this subpart, and in particular § 57.1305; the number and type of dental auxiliaries to be utilized in the project; the available resources to conduct the proposed project; and a detailed budget.

§ 57.1305 What requirements must a project meet?

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) The project must be conducted in accordance with section 783(a)(3) of the Act, the regulations of this subpart, the approved application, and the terms and conditions of the award.

(b) Each project must have a didactic and clinical component which has as its objectives the training of dental students who will, upon completion of the training be able to:

(1) Demonstrate the ability to delegate duties commensurate with the skills of their auxiliaries and ensure the quality of their clinical performance and products;

(2) Demonstrate skills in personnel management, including an understanding of human behavior, interpersonal relations, group dynamics and communication;

(3) Demonstrate skills in patient management and preventive dental care including an understanding of motivation and personal health education as related to team practice.

(4) Demonstrate those skills in dental office management which relate to operating a team practice, including patient scheduling and flow, and cost benefit analysis; and

(5) Demonstrate an understanding of the basic principles of facility and equipment design necessary for operating a team practice in a private practice setting.

(c) Each dental student must have successfully completed didactic and clinical training in four-handed, sitdown dentistry before participating in a project supported under this subpart.

(d) Each dental student participating in a project supported under this subpart must receive training in a team composed, at a minimum, of one dental assistant, one expanded function dental auxiliary and a shared dental hygienist.

(e) Each project must be designed to delegate to dental auxiliaries all functions permitted by the law or regulations of the State in which the project is conducted.

§ 57.1306 What are the criteria for deciding which applications are to be funded?

Within the limits of funds available under section 783(a)(3), the Secretary, after consultation with the Council, may award grants to those applicants whose projects will in his or her judgment best promote the purposes of section 783(a)(3) of the Act, taking into consideration, among other pertinent factors:

(a) The potential effectiveness of the proposed project in carrying out the training purposes of section 783(a)(3) of the Act;

(b) The degree to which the proposed project adequately provides for meeting the project requirements set forth in § 57.1305;

(c) The administrative and managerial capability of the applicant to carry out the proposed project;

(d) The qualifications of the project director, staff and faculty;

(e) The reasonableness of the proposed budget in relation to the proposed project; and

(f) The scope of the expanded functions to be performed by expanded function dental auxiliaries, and, in particular, the extent to which the expanded function dental auxiliary will be performing advanced skills.

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[2] Applications and instructions may be obtained from the Grants Management Officer, Bureau of Health Manpower, Health Resources Administration, Center Bldg., Rm. 4-27, 3700 East-West Highway, Hyattsville, Maryland 20782.

§ 57.1307 How will grant awards be made?

(a) General (1) Within the limits of funds available for this purpose, the Secretary may award grants to those applicants whose projects will, in his or her judgment, best promote the purposes of section 783(a)(3) of the Act as determined in accordance with § 57.1306.

(2) All grant awards will be in writing and set forth the amount of funds granted and the period for which grant funds will be available for obligation by the grantee.

(3) Projects receiving grants under this subpart may be approved for an initial period of grant support for up to two years. Additional support may be obtained by submission of a competing extension application.

(4) Neither the approval of any application nor any grant award obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application. For continuation support grantees must make separate application at the time and in the form as the Secretary may require.

(b) The amount of any award will be determined by the Secretary on the basis of his or her estimate of the sum necessary for the cost (including both direct and indirect costs) of projects to plan, develop, and operate or maintain programs for dental team practice training grants.

(c) The Secretary may, within the limits of funds available for this purpose, make a grant award for an additional budget period for any previously approved project if, on the basis of progress and accounting records, the Secretary finds that the project's activities during the current budget period justify continued support of the project for an additional budget period.

§ 57.1308 How will grant payments be made?

The Secretary will from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement.

§ 57.1309 What are the purposes for which grant funds may be spent?

(a) Grant funds must be expended solely for costs of projects to plan, develop, and operate or maintain programs for dental team practice training grants in accordance with the applicable provisions of the Act, these regulations, and the terms and conditions of the award.

(b) Grant funds may not be expended for sectarian instruction or any religious purpose.

(c) Any unobligated funds remaining in the grant account at the close of a budget period may be carried forward and will be available for obligation during subsequent budget periods of the project period. The amount of any subsequent award will take into consideration the amount remaining in the grant account. At the end of the last budget period, any unobligated funds remaining in the grant account must be refunded to the Federal Government.

§ 57.1310 What nondiscrimination requirements apply to grantees?

(a) Recipients of grants under this subpart are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations are applicable:

(1) Section 704 of the Act (42 U.S.C. 292d) and 45 CFR Part 83 (prohibiting discrimination on the basis of sex in the admission of individuals to training programs under Title VII of the Act);

(2) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its implementing regulation, 45 CFR Part 80 (prohibiting discrimination in Federally assisted programs on the grounds of race, color, or national origin);

(3) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) and its implementing regulation, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in Federally assisted education programs); and

(4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and its implementing regulation, 45 CFR Part 84 (prohibiting discrimination in Federally assisted programs on the basis of handicap).

(b) The grantee shall not discriminate on the basis of religion in the admission of individuals to its training programs.

§ 57.1311 How must grantees account for grant funds received?

(a) *Accounting for grant award payments.* The grantee must record all payments made by the Secretary in accounting records separate from the records of all other funds, including funds derived from other grant awards. The grantee must account for the sum total of all amounts paid by making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart.

(b) *Grant closeout.*

(1) *Date of final accounting.* A grantee must submit with respect to each grant under this subpart, a full account, in accordance with this subsection, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* The grantee must pay to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for under paragraphs (a) and (b) of this section; and

(ii) Any other amounts due in accordance with 45 CFR Part 74 and the terms and conditions of the grant award. This total sum constitutes a debt owed by the grantee to the Federal Government and is recoverable from the grantee or its successors or assignees by setoff or other lawful action.

§ 57.1312 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, apply to all grants under this subpart.

§ 57.1313 What recordkeeping, audit, and inspection requirements apply to grantees?

Each entity that receives a grant must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act concerning recordkeeping, audit and inspection.

§ 57.1314 What additional conditions apply to grantees?

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his or her judgment these conditions are necessary to assure or protect advancement of the grant purposes, the interests of the public health, or the conservation of grant funds.

Subpart O—Grants To Assist New Schools of Medicine, Osteopathy, and Dentistry

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216; sec. 771(a), 85 Stat. 443, 42 U.S.C. 295f-1.

SOURCE: 37 FR 15863, Aug. 5, 1972, unless otherwise noted.

§ 57.1401 Applicability.

The regulations of this subpart are applicable to the award of grants under section 771(a)(1) of the Public Health Service Act (42 U.S.C. 295f-1) to assist new schools of medicine, osteopathy, or dentistry in meeting their initial costs of operation.

§ 57.1402 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act as amended.

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) "School" means a public or other nonprofit school of medicine, dentistry, or osteopathy, which provides or will provide a course of study or portion thereof which leads, respectively, to a degree of doctor of medicine, doctor of dental surgery or an equivalent degree, or doctor of osteopathy, and with respect to which there has been a reasonable finding regarding accreditation as provided in section 775(b)(2)(A) of the Act.

(d) "Full-time student" means a student who is enrolled or is expected to be enrolled in a new school on a full-time basis, as determined by the new school, and is pursuing a course of study leading to a degree specified in paragraph (c) of this section.

(e) "First academic year of operation" means the first year in which the school provides instruction to students.

(f) "Council" means the National Advisory Council on Health Professions Education (established by section 725 of the Act).

(g) "Fiscal year" means the Federal fiscal year beginning July 1 and ending on the following June 30.

(h) "Budget period" means the interval of time into which an approved activity is divided for budgetary purposes, as specified in the grant award document.

(i) "Project period" means the time (not exceeding 4 years) for which support for startup assistance has been approved, as specified in the grant award document.

§ 57.1403 Eligibility.

(a) To be eligible for a grant for startup assistance under the Act, the applicant must:

(1) Be a new school as provided in paragraph (b) of this section;

(2) Furnish the Secretary such reasonable assurances as he may require to make a determination that the school will enroll at least 24 full-time students in its first academic year of operation; and

(3) Be located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, or the Trust Territories of the Pacific Islands.

(b) For purposes of this section a school shall be considered a "new school" in the fiscal year preceding the first year in which such school has students enrolled and for the following 3 fiscal years, provided that such school began instruction after November 18, 1971.

§ 57.1404 Application.

(a) Each school desiring a grant for startup assistance shall submit an application in such form and at such time as the Secretary may require.[1]

(b) Such application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations of this subpart.

(c) Such application shall state the purposes for which the application is made, and shall contain a budget and a narrative plan of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart.

§ 57.1405 Determination of number of students.

For purposes of this subpart the number of full-time students enrolled or to be enrolled in a new school for any given year shall be the number the Secretary determines are or will be enrolled in such school on the date instruction begins or on such other date as may be mutually agreed upon. Estimates by the Secretary with respect to such enrollment may be made on the basis of assurances provided by such school.

§ 57.1406 Grant awards.

(a) Within the limits of funds available for such purpose, the Secretary, after consultation with the Council, may award grants to those applicants whose projects will in his judgment best promote the purposes of section 771(a) of the Act taking into consideration:

(1) The relative merit of the applicant's plan;

(2) The other resources available to the applicant to assure the sound establishment and continuing maintenance of the school;

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[1] Applications and instructions are available from the Division of Physician and Health Professions Education, Bureau of Health Manpower, National Institutes of Health, 9000 Rockville Pike, Building 31, Bethesda, MD 20014.

(3) The ability of the new school to use grant assistance to (i) accelerate the date it will begin instruction; or (ii) increase the number of students in its entering class over the number to be enrolled if grant assistance is not available. In addition, special consideration will be given to new schools which provide reasonable assurance that, because of the use the new school will make of existing facilities, including Federal medical or dental facilities, it will be able to accelerate the date it will begin its teaching program.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for the cost of startup assistance, but shall not exceed the following amounts:

(1) For the year preceding the first year in which students are enrolled, $10,000 times the estimated number of full-time students which will enroll in the school in the first year of operation;

(2) For the first year in which students are enrolled, $7,500 times the number of full-time students enrolled in the school;

(3) For the second year in which students are enrolled; $5,000 times the number of full-time students enrolled in the school; and

(4) For the third year in which students are enrolled, $2,500 times the number of full-time students enrolled in the school.

(c) All grant awards shall be in writing, shall set forth the amount of funds granted and the period (not to exceed 4 years) for which such funds will be available for obligation by the grantee.

(d) Neither the approval of any application nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion thereof. For continuation support, grantees must make separate application annually and at such times and in such forms as the Secretary may dictate.

§ 57.1407 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement.

§ 57.1408 Expenditure of grant funds.

Any funds granted pursuant to this subpart shall be expended solely for costs of startup assistance in accordance with the applicable provisions of the Act, the regulations of this subpart, and the terms and conditions of the award. Any unobligated funds remaining in the grant account at the close of a budget period may be carried forward and will be available during a subsequent budget period of the project period. The amount of any subsequent award will take into consideration the amount remaining in the grant account. At the end of the last budget period of the project period any unobligated funds remaining in the grant account must be refunded to the Federal Government.

§ 57.1409 Nondiscrimination.

(a) Attention is called to the requirements of section 779A of the Act and 45 CFR Part 83 which together provide that the Secretary may not make a grant, loan guarantee, or interest subsidy payment under title VII of the Act to, or for the benefit of, any school of medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, podiatry, or public health or any training center for allied health personnel or any other entity unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary that the school, training center, or other entity will not discriminate on the basis of sex in the admission of individuals to its training programs.

(b) Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d, et seq.), which provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which is applicable to grants made under this subpart, has been issued by the Secretary with the approval of the President (45 CFR Part 80).

(c) Grant funds used for remodeling, alteration, or repairs shall be subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, and with the applicable rules, regulations, and procedures prescribed pursuant thereto.

§ 57.1410 Inventions and discoveries.

Any grant award pursuant to § 57.1406 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR Parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§ 57.1411 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from a project supported by a grant under this subpart, subject, however, to a royalty free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 57.1412 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project, the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart.

(b) *Accounting for equipment.* As used in this section the term "equipment" means an article of property procured or fabricated which is complete in itself, is of a durable nature, and has an expected service life of more than 1 year. Equipment on hand on the date of termination for which accounting is required in accordance with the procedures set forth in Chapter 1-410-50 of the Department of Health and Human Services Grants Administration Manual[2] shall be identified and reported by the grantee in accordance with such procedures and be accounted for by one or a combination of the following methods, as determined by the Secretary:

(1) *Retention of equipment for other health projects.* Material may be used, without adjustment of accounts, on other grant-supported projects (whether or not federally supported) within the scope of section 771(a) of the Act, and no other accounting for such material shall be required: *Provided, however,* (i) That during such period of use no charge for depreciation, amortization, or for other use of the equipment shall be made against any existing or future Federal grant or contract, and (ii) if within the period

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[2] The Department of Health and Human Services Grants Administration Manual is available for public inspection and copying at the Department's and regional offices' information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

of their useful life, the equipment is transferred by sale or otherwise for use outside the scope of section 771(a) of the Act, the Federal portion of the fair market value at the time of transfer shall be refunded to the Federal Government.

(2) *Sale or other disposition of equipment; crediting of proceeds or value.* The equipment may be sold by the grantee and the net proceeds of sale credited to the grant account for project use, or they may be used or disposed of in any manner by the grantee by crediting to the grant account the Federal share of the fair market value on the termination date. To the extent equipment purchased from grant funds is used for credit or trade-in on the purchase of new equipment, the accounting obligation shall apply to the same extent to such new equipment.

(3) *Return or transfer of equipment.* The equipment may be returned to the Federal Government by the grantee, or in accordance with the provisions of Chapter 1-410-50B of the Department of Health and Human Services Grants Administration Manual may be transferred to another grantee for the purpose of continuing the project for which the equipment was purchased.

(c) *Accounting for grant-related income*—(1) *Interest.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in sec. 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(2) *Royalties.* Royalties earned from publications or similar material produced from a grant must first be used to reduce the Federal share of the grant to cover the costs of publishing or producing the materials. Royalties in excess of the costs of publishing or producing the materials shall be distributed as in paragraph (c)(3) of this section.

(3) *Other income.* Other income earned by the grantee shall be disposed of in accordance with one of the alternatives specified in Chapter 1-420 of the Grants Administration Manual as determined by the Secretary in the grant award.

(d) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of (i) any amount not accounted for pursuant to paragraph (a) of this section; (ii) any credits for material on hand as provided in paragraph (b) of this section; (iii) any credits for earned interest pursuant to paragraph (c)(1) of this section; and (iv) any other settlements required pursuant to paragraphs (c) (2) and (3) of this section. Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assigns by setoff or other action as provided by law.

§ 57.1413 Records, reports, inspection, and audit.

(a) *Records and reports.* Each grant awarded pursuant to this subpart shall be subject to the condition that the grantee shall maintain such operational and accounting records, identifiable by grant number, and file with the Secretary such operational and fiscal reports relating to the use of grant funds, as the Secretary may find necessary to carry out the purposes of section 771(a) of the Act and the regulations of this subpart. All records shall be retained for 3 years after the close of the budget period. Such records may be destroyed at the end of such 3-year period if the applicant has been notified of the completion of the

Federal audit by such time. If the applicant has not been so notified, such records shall be retained (1) for 5 years after the close of the budget period, or (2) until the grantee is notified of the completion of the Federal audit, whichever comes first. In all cases where audit questions have arisen before the expiration of such 5-year period, records shall be retained until resolution of all such questions.

(b) *Inspection and audit.* Any application for a grant award under this subpart shall constitute the consent of the applicant to inspections of the facilities, equipment, and other resources of the applicant at reasonable times by persons designated by the Secretary and to interviews with the principal staff members and students to the extent that such resources, personnel, and students are, or will be involved in the project. In addition, the acceptance of any grant award under this subpart shall constitute the consent of the grantee to inspection and fiscal audits by such person of the supported activity and of progress and fiscal records relating to the use of grant funds.

§ 57.1414 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the grant purposes, the interest of the public health, or the conservation of grant funds.

§ 57.1415 Early termination and withholding of payments.

Whenever the Secretary finds that a grantee has failed in a material respect to comply with the applicable provisions of the Act, the regulations of this subpart, or the terms of the grant, he may, on reasonable notice to the grantee, withhold further payments and take such other action, including the termination of the grant, as he finds appropriate to carry out the purposes of the Act and regulations. Noncancelable obligations of the grantee properly incurred prior to the receipt of the notice of termination will be honored. The grantee shall be promptly notified of such termination in writing and given the reasons therefor.

Subpart P—Loan Guarantees and Interest Subsidies to Assist in Construction of Teaching Facilities for Health Profession Personnel

AUTHORITY: Sec. 727, 77 Stat. 170, as amended, (42 U.S.C. 293g).

SOURCE: 38 FR 31836, Nov. 19, 1973, unless otherwise noted.

§ 57.1501 Applicability.

The regulations of this subpart are applicable to loan guarantees and interest subsidy payments made pursuant to section 729 of the Public Health Service Act (42 U.S.C. 293i) to assist nonprofit private entities which are eligible for grants under Subpart B of this part in carrying out projects for construction of teaching facilities for health professions personnel.

§ 57.1502 Definitions.

As used in this subpart:

(a) All terms not defined herein shall have the same meanings as given them in section 724 of the act.

(b) "Act" means the Public Health Service Act, as amended.

(c) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

(d) "School" means a school of medicine, dentistry, osteopathy, pharmacy, optometry, podiatry, veterinary medicine, or public health which provides a course of study or a portion thereof which leads respectively to a degree of doctor of medicine, doctor of dental surgery or an equivalent degree, doctor of osteopathy, doctor of optometry or an equivalent degree, doctor of podiatry or an equivalent degree, bachelor of science in pharmacy or an equivalent degree, doctor of veterinary medicine or equivalent degree, or a graduate degree in public health, and which is accredited as provided in section 721(b)(1) of the act.

(e) "Affiliated hospital" or "affiliated outpatient facility" means a hospital or outpatient facility (as defined in section 645 of the act) which, although not owned by such school, has a written agreement with a school of medicine, osteopathy, or dentistry eligible for assistance under Subpart B of this part, providing for effective control by the school of the health professions teaching program in the hospital or outpatient facility.

(f) "Nonprofit" as applied to any school, hospital, outpatient facility, or other entity means one which is owned and operated by one or more corporations or associations no part of the net earnings of which inures, or may lawfully inure to the benefit of any private shareholder or individual.

(g) "Council" means the National Advisory Council on Health Professions Education (established pursuant to section 725 of the act).

§ 57.1503 Eligibility.

(a) *Eligible applicants.* In order to be eligible for a loan guarantee or interest subsidy under this subpart, the applicant shall:

(1) Be a nonprofit private school of medicine, dentistry, osteopathy, pharmacy, optometry, podiatry, veterinary medicine, or public health, or any combination of such schools, or a nonprofit private affiliated hospital or affiliated outpatient facility: *Provided, however,* That in the case of an affiliated hospital or affiliated outpatient facility, an application which is approved by the school of medicine, osteopathy or dentistry with which the hospital or outpatient facility is affiliated and which otherwise complies with the requirements of Subpart B of this part may be filed by any nonprofit private entity qualified to file an application under section 605 of the act; and

(2) Otherwise meet the applicable requirements set forth in section 721(b) of the act and § 57.103 with respect to eligiblity for grants for construction of teaching facilities for health professions personnel.

(b) *Eligible loans.* Subject to the provisions of this subpart, the Secretary may guarantee payment, when due, of principal and interest on, or may pay interest subsidies with respect to, or may both guarantee and pay interest subsidies with respect to any loan or portion thereof made to an eligible applicant by a non-Federal lender: *Provided,* That no such guarantee or interest subsidy shall apply to any loan the interest on which is exempt from Federal income taxation.

§ 57.1504 Application.

Each applicant desiring to have a loan guaranteed or to have interest subsidies paid on its behalf, or any combination of such loan guarantee or interest subsidies, shall submit an application for such assistance in such form and manner and at such time as the Secretary may require.[1]

(a) The application shall contain or be supported by such information as the Secretary may require to enable him to make the determinations required of him under the act and this subpart.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any loan guarantee or agreement to pay interest subsidies, including the applicable regulations of this subpart.

§ 57.1505 Approval of applications.

(a) *General.* Any application for loan guarantee or interest subsidies, or for a combination of both, may be approved by the Secretary, after consultation with the Council, only if he makes each of the applicable determinations set forth in section 721(c) of the act. In addition:

(1) Any such approval shall be subject to compliance by the applicant with the applicable provisions set forth in §§ 57.106, 57.107, 57.108, and 57.110: *Provided however,* That for purposes of the title assurance in § 57.107(a) the period shall be not less than 20 years or the term of the guaranteed loan, whichever is longer or in the case of interim facilities, the term of the guaranteed loan, and

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[1] Applications and instructions are available from the Division of Physician and Health Professions Education, Bureau of Health Manpower Education, National Institutes of Health, Bldg. 31, 9000 Rockville Pike, Bethesda, Md. 20014.

(2) Any such application may be approved by the Secretary only if he determines:

(i) That the applicant will have sufficient financial resources to enable him to comply with the terms and conditions of the loan;

(ii) That the applicant has the necessary legal authority to finance, construct, and maintain the proposed project, to apply for and receive the loan, and to pledge or mortgage any assets or revenues to be given as security for such loan;

(iii) That the loan will be made only with respect to the initial permanent financing of the project;

(iv) That the loan will be secured by a lien against the facilities to be constructed or against other security satisfactory to the Secretary specified in § 57.2210;

(v) That the rate of interest on the loan does not exceed such percent per annum as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States; and

(vi) Such additional determinations as the Secretary finds necessary with respect to particular applications in order to protect the financial interests of the United States.

(b) *Loan guarantees.* In addition to the requirements of paragraph (a) of this section, any application for a loan guarantee may be approved by the Secretary only if he determines that the loan with respect to which such guarantee is sought would not be available to the applicant on reasonable terms and conditions without such guarantee. To assist the Secretary in making such determination, each applicant for a loan guarantee shall submit statements from at least three non-Federal institutions normally engaged in making long-term loans for construction, describing whether, and the terms and conditions under which, each institution would make a loan to the applicant for the project described in the application.

(c) *Interest subsidies.* In addition to the requirements of paragraph (a) of this section, any application for interest subsidies may be approved by the Secretary only if he determines that without such interest subsidy payments the applicant would not, over a substantial portion of the loan term, be able to repay the principal and interest of the loan without jeopardizing the quality of the educational program.

§ 57.1506 Priority.

(a) Priority in approving applications for loan guarantee and/or interest subsidies shall be determined in accordance with the factors specified in section 721(d) of the act, and the following: (1) The relative need for increased enrollment and the availability of students; (2) the relative effectiveness of the project relative to the cost to the Federal Government; and (3) the relative ability of the applicant to make efficient and productive use of the facility constructed.

(b) In the case of applications to aid in the construction of new schools of medicine, osteopathy, or dentistry, the Secretary shall give special consideration to those applications which contain or are reasonably supported by assurances that, because of the use that will be made by such school of already existing facilities (including Federal medical or dental facilities), the school will be able to accelerate the date on which it will begin its teaching program.

§ 57.1507 Limitations applicable to loan guarantee.

(a) The amount of loan with respect to which a guarantee is made under this subpart shall be determined by the Secretary based upon such considerations as the availability of funds and the applicant's need therefor; *Provided,* That: (1) Subject to paragraph (a)(2) of this section, no loan with respect to which a guarantee is made for any project under this subpart may be in an amount which, when added to the amount of any grant made with respect to such project under Part B of title VII of the act or any other law of the United States, or to the total of such grants, exceeds 90 percent of the eligible cost of construction of such project as determined by the Secretary;

(2) Notwithstanding paragraph (a)(1) of this section, the Secretary may in particular cases guarantee loans in excess of the amount specified in paragraph (a)(1) of this section where he determines that, because of special circumstances, such additional loan guarantee will further the purposes of Part B of title VII of the act. In making such determinations, the Secretary will in each case consider the following factors:

(i) The need for the project in the area to be served;

(ii) The availability of financing for the project on reasonable terms and conditions without such additional loan guarantee;

(iii) Whether the project can be constructed without such additional loan guarantee; and

(iv) Other relevant factors consistent with the purpose of Part B of title VII of the act and this subpart.

(3) In determining the cost of construction of the project there shall be excluded from such cost all fees, interest, and other charges relating or attributable to the financing of the project except the following:

(i) Reasonable fees attributable to services rendered by legal counsel in connection with such loan;

(ii) With the approval of the Secretary, reasonable fees attributable to the services of a financial advisor in assisting the applicant in securing the loan and arranging for repayment thereof; and

(iii) Interest attributable to the interim financing of construction of the project prior to the initial permanent financing thereof.

(b) No loan guarantee under this subpart shall apply to more than 90 percent of the loss of principal of and interest on such loan incurred by the holder of such loan upon default by the applicant.

§ 57.1508 Amount of interest subsidy payments; limitations.

The length of time for which interest subsidy payments will be made under the agreement, the amount of loan with respect to which such payments will be made, and the level of such payments shall be determined by the Secretary on the basis of the availability of funds and his determination of the applicant's need therefor taking into consideration his analysis of the present and reasonable projected future financial ability of the applicant to repay the principal and interest of the loan without jeopardizing the quality of its educational program: *Provided however,* That each such interest subsidy payment shall not exceed the amount necessary to reduce by 3 percent per annum the net effective interest rate otherwise payable on the loan or the portion thereof with respect to which such interest subsidy is paid.

§ 57.1509 Forms of credit and security instruments.

Each loan with respect to which a guarantee is made or interest subsidies are paid under this subpart shall be evidenced by a credit instrument and secured by a security instrument in such forms as may be acceptable to the Secretary.

§ 57.1510 Security for loans.

Each loan with respect to which a guarantee is made or interest subsidies are paid under this subpart shall be secured in a manner which the Secretary finds reasonably sufficient to insure repayment. The security may be one or a combination of the following:

(a) A first mortgage on the facility and site thereof.

(b) Negotiable stocks or bonds of a quality and value acceptable to the Secretary.

(c) A pledge of unrestricted and unencumbered income from an endowment or other trust fund acceptable to the Secretary.

(d) A pledge of a specified portion of annual general or special revenues of the applicant acceptable to the Secretary.

(e) Such other security as the Secretary may find acceptable in specific instances.

§ 57.1511 Opinion of legal counsel.

At appropriate stages in the application and approval procedure for a loan guarantee or interest subsidy, the applicant shall furnish to the Secretary a memorandum or opinion of legal counsel with respect to the legality of any proposed note issue, the legal authority of the applicant to issue the note and secure it by the proposed collateral, and the legality of the issue upon delivery. "Legal counsel" means either a law firm or individual lawyer, thoroughly experienced in the long-term financing of construction projects, and whose approving opinions have previously been accepted by lenders or lending institutions. The legal memorandum or opinion to be provided by legal counsel in each case shall be as follows:

(a) A memorandum, submitted with the application for a loan guarantee or interest subsidy, stating that the applicant is or will be lawfully authorized to finance, construct, and maintain the project, and to issue the proposed obligations and to pledge or mortgage the assets and/or revenues offered to secure the loan, citing the basis for such authority; and

(b) A final approving opinion, delivered to the Secretary at the time of delivery of the evidence of indebtedness to the lender, stating that the credit and security instruments executed by the applicant are duly authorized and delivered and that the indebtedness of the applicant is valid, binding, and payable in accordance with the terms on which the loan guarantee was approved by the Secretary.

§ 57.1512 Length and maturity of loans.

The repayment period for loans with respect to which guarantees are made or interest subsidies paid under this subpart shall be limited to 30 years: *Provided*, That: (a) The Secretary may, in particular cases where he determines that a repayment period of less than 30 years is more appropriate to an applicant's total financial plan, approve such shorter repayment period;

(b) The Secretary may, in particular cases where he determines that, because of unusual circumstances, the applicant would be financially unable to amortize the loan over a repayment period of 30 years, approve a longer requirement period which shall in no case exceed 40 years; and

(c) In no case shall a loan repayment period exceed the useful life of the facility to be constructed with the assistance of the loan.

§ 57.1513 Repayment.

Unless otherwise specifically authorized by the Secretary, each loan with respect to which a guarantee is made or interest subsidies are paid shall be repayable in substantially level total annual installments of principal and interest, sufficient to amortize the loan through the final year of the life of the loan.

§ 57.1514 Loan guarantee and interest subsidy agreements.

For each application for a loan guarantee or interest subsidy, or combination thereof, which is approved by the Secretary under this subpart, an offer to guarantee such loan and/or make interest subsidy payments with respect thereto will be sent to the applicant, setting forth the pertinent terms and conditions for the loan guarantee and/or interest subsidy, and will be conditioned upon the fulfillment of such terms and conditions. The accepted offer will constitute the loan guarantee agreement, the interest subsidy agreement, or the loan guarantee and interest subsidy agreement, as the case may be. Each such agreement shall include the applicable provisions set forth below:

(a) *Loan guarantee.* Each agreement pertaining to a loan guarantee shall include the following provisions:

(1) That the loan guarantee evidenced by the agreement shall be incontestable (i) in the hands of the applicant on whose behalf such loan guarantee is made except for fraud or misrepresentation on the part of such applicant, and (ii) as to any person who makes or contracts to make a loan to such applicant in reliance on such guarantee, except for fraud or misrepresentation on the part of such other person.

(2) That the applicant shall be permitted to prepay up to 15 percent of the original principal amount of such loan in any calendar year without additional charge. The applicant and the lender may further agree that the ap-

plicant shall be permitted to prepay in excess of 15 percent of the original amount of the loan in any calendar year without additional charge, but no such payment in excess of 15 percent shall be made without the prior written approval of the Secretary.

(3) That if the applicant shall default in making periodic payment, when due, of the principal and interest on the loan guaranteed under the agreement, the holder of the loan shall promptly give the Secretary written notification of such default. The Secretary shall, immediately upon receipt of such notice, provide the holder with written acknowledgement of such receipt.

(4) That if such default in making periodic payment when due of the principal and interest on the guaranteed loan is not cured within 90 days after receipt by the Secretary of notice of such default, the holder of the loan shall have the right to make demand upon the Secretary, in such form and manner as the Secretary may prescribe, for payment of 90 percent of the amount of the overdue payments of principal and accrued interest, together with such reasonable late charges as are made in accordance with the terms of the credit instrument or security instrument evidencing or securing such loan. The Secretary shall pay such amount from funds available to him for these purposes.

(5) That in the event of exercise by the holder of the loan of any right to accelerate payment of such loan as a result of the applicants default in making periodic payment when due of the principal and interest on the guaranteed loan, the Secretary shall, upon demand by the holder not less than 90 days after receipt by the Secretary of notification of such default, pay to such holder 90 percent of the total amount of principal and of interest on the loan remaining unpaid after the holder has exercised his right to foreclose upon and dispose of the security and has applied the proceeds thereby received to reduce the outstanding balance of the loan, in accordance with applicable law and the terms of the security instrument.

(6) That the Secretary shall not guarantee any funds which are disbursed by a lender following notification by the Secretary to such lender that the Assurance executed by the Applicant under section 799A of the Act is no longer satisfactory.

(b) *Interest subsidy.* Each agreement pertaining to the payment of interest subsidies with respect to a loan shall include the following provisions:

(1) That the holder of the loan shall have a contractual right to receive from the United States interest subsidy payments in amounts sufficient to reduce by up to 3 percent per annum the net effective interest rate determined by the Secretary to be otherwise payable on such loan.

(2) That payments of interest subsidies pursuant to paragraph (b)(1) of this section will be made by the Secretary, in accordance with the terms of the loan with respect to which the interest subsidies are paid, directly to the holder of such loan, or to a trustee or agent designated in writing to the Secretary by such holder, until such time as the Secretary is notified in writing by the holder that such loan has been transferred. Pursuant to such written notification of transfer, the Secretary will make such interest payments directly to the new holder (transferee) of the loan: *Provided, however,* That it shall be the responsibility of the holder to remit any payments of interest subsidy to the new holder which the Secretary may have made to the holder after such transfer and prior to receipt of such written notice, and the Secretary shall not be liable to any party for amounts remitted to the holder prior to receipt of such written notice and acknowledgment in writing by the Secretary of receipt of such notice.

(3) That the holder of the loan will promptly notify the Secretary of any default or prepayment by the applicant with respect to the loan.

(4) In the event of any exercise by the holder of the loan of the right to accelerate payment of such loan, whether as a result of default on the part of the applicant or otherwise, the Secretary's obligations with respect to the payment of interest subsidies shall cease.

(5) Where, during the life of the loan with respect to which interest subsidies are to be paid, the applicant ceases to use the facility for the purposes for which constructed, the Secretary's obligation with respect to the payment of interest subsidies shall cease: *Provided, however,* That where the applicant is continuing to use the facility for purposes eligible for support under Part B of title VII of the act, the Secretary may make a determination, based upon the health manpower needs of the community served by the facility as well as other relevant factors, to continue to make interest subsidy payments in accord with the agreement.

(6) Where during the life of the loan with respect to which interest subsidies are to be paid, it is determined, after an opportunity for a hearing pursuant to 45 CFR Part 83, that the Assurance executed by the Applicant under Section 799A of the Act, is no longer satisfactory, the Secretary's obligation with respect to the payment of interest subsidies shall cease: *Provided, however,* That the Secretary shall resume making interest subsidy payments if he determines that a subsequent Assurance submitted by the applicant is satisfactory.

(7) Where during the life of the loan with respect to which interest subsidies are to be paid, it is determined by the Secretary, after an opportunity for a hearing pursuant to 45 CFR Parts 80 and 81, that the applicant has ceased to comply with the Assurance it has executed under 45 CFR 80.4(d) concerning nondiscrimination on the basis of race, color or national origin, the Secretary's obligation with respect to the payment of interest subsidies shall cease: *Provided, however,* That the Secretary shall resume making interest subsidy payments if he subsequently determines that the applicant has come into compliance with the requirements of title VI of the Civil Rights Act of 1964 and implementing regulations.

(8) Where during the life of the loan with respect to which interest subsidies are to be paid, it is determined by the Secretary after an opportunity for a hearing pursuant to title IX of the Education Amendments of 1972, that the applicant has ceased to comply with such title, and its implementing regulations, the Secretary's obligation with respect to the payment of interest subsidies shall cease: *Provided, however,* That the Secretary shall resume making interest subsidy payments if he subsequently determines that the applicant has come into compliance with the requirements of title IX of the Education Amendments of 1972 and implementing regulations.

(c) *General.* In addition to the applicable requirements of paragraphs (a) and (b) of this section, each agreement, whether pertaining to a loan guarantee or interest subsidy or both, shall contain such other provisions as the Secretary finds necessary in order to protect the financial interests of the United States.

§ 57.1515 Loan closing.

Closing of any loan with respect to which a guarantee is made or interest subsidies are paid under this subpart shall be accomplished at such time as may be agreed upon by the parties to such loan and found acceptable to the Secretary.

§ 57.1516 Right of recovery-subordination.

(a) The United States shall be entitled to recover from the applicant for a loan guarantee under this subpart the amount of any payment made pursuant to such guarantee, unless the Secretary waives such right of recovery as provided in § 57.1517.

(b) Upon making of any payments pursuant to a loan guarantee under this subpart, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

§ 57.1517 Waiver of right to recovery.

In determining whether there is good cause for waiver of any right of recovery which he may have against any applicant by reason of any payments made pursuant to a loan guarantee under this subpart, the Secretary shall take into consideration the extent to which:

(a) The facility with respect to which the loan guarantee was made will continue to be devoted by the applicant or other owner to the teaching of health professions personnel, or to other purposes in the sciences related to health for which funds are available under Part B of title VII of the act and these regulations;

(b) A hospital or outpatient facility will be used as provided for under title VI of the act;

(c) There are reasonable assurances that for the remainder of the repayment period of the loan other facilities not previously utilized for the purpose for which the facility was constructed will be so utilized and are substantially equivalent in nature and extent for such purposes; and

(d) Such recovery would seriously curtail the training of qualified health professions personnel in the area served by the facility.

Subpart Q—Grants for Predoctoral, Graduate, and Faculty Development Education Programs in Family Medicine

AUTHORITY: Sec. 215 of the Public Health Service Act. 58 Stat. 690 as amended by 63 Stat. 35 (42 U.S.C. 216); Sec. 786(a) of the Public Health Service Act. 90 Stat. 2316 (42 U.S.C. 295g-6(a)).

SOURCE: 45 FR 68895, Oct. 16. 1980, unless otherwise noted.

§ 57.1601 To what programs do these regulations apply?

These regulations apply to the award of grants under section 786(a) of the Public Health Service Act (42 U.S.C. 285g6(a)) to schools of medicine or osteopathy, hospitals, and other public or private nonprofit entities for projects to: (a) Plan, develop, and operate, or participate in predoctoral, graduate, or faculty development educational programs in family medicine; and (b) provide financial assistance to trainees participating in predoctoral or graduate educational programs who are in need of financial assistance and who plan to practice family medicine or to trainees in faculty development programs who plan to teach in family medicine training programs.

§ 57.1602 Definitions.

"Act" means the Public Health Service Act, as amended.

"Clerkship" means supervised clinical training in a specific field of medicine for predoctoral medical or osteopathic students.

"Faculty development program" means a systematic training program to increase faculty competence in teaching skills and in other areas related to academic responsibilities.

"Family medicine" means the field of medicine in which the physician:

(a) Serves as a physician of first contact with families and with patients of all ages and provided a means of entry into the health care system;

(b) Evaluates the patient's total health needs, provides personal medical care within one or more fields of medicine, and refers the patient, when indicated, to appropriate sources of care while preserving the continuity of care;

(c) Assumes responsibility with the patient for comprehensive and continuous health care and acts as a leader or coordinator of others providing health services; and

(d) Considers the patient's total health care within the context of his or her environment, including the community and the family or comparable social units.

"Hospital" means a public or other nonprofit hospital which is accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association.

"Nonprofit", as applied to any entity, means one in which no part of the net earnings inures or may lawfully inure to the benefit of any private shareholder or individual.

"Osteopathic intern program" means an internship which emphasizes family medicine and is approved by the American Osteopathic Association.

"Preceptorship" means an educational experience in which the trainee works individually with a designated physician, the preceptor, who teaches and personally supervises clinical activity.

"Predoctoral training program" means an educational program in family medicine, including courses, clerkships or preceptorships in family medicine, which is part of a course of study leading to the degree of doctor of medicine or osteopathy, and student assistantships in family medicine.

"Residency training program" means:

(a) A residency program in family practice which is fully or provisionally accredited by the Liaison Committee on Graduate Medical Education; or

(b) A postdoctoral program in osteopathic general practice which emphasizes family medicine and is approved by the American Osteopathic Association.

"School of medicine or osteopathy" means a public or private nonprofit school which provides training leading respectively to a degree of doctor of medicine or to a degree of doctor of osteopathy and which is accredited as provided in section 772(b) of the Act (42 U.S.C. 295f-5).

"Secretary" means the Secretary of Health and Human Services and any other officer or employer of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means any one of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

"Student assistantship" means a research program in family medicine for predoctoral medical or osteopathic students.

"Trainee" means a medical or osteopathic student, intern, resident, or physician participating in a training program supported by a grant under these regulations.

§ 57.1603 Who is eligible to apply for a grant?

(a) For predoctoral training programs, an applicant must be a school of medicine or osteopathy located in a State.

(b) For graduate and faculty development training programs, an applicant must be located in a State and be a school of medicine or osteopathy, a hospital, or a public or private nonprofit entity which provides either health or educational programs as one of its major functions.

§ 57.1604 What requirements must a project meet?

(a) *General requirements.* A project supported under this subpart must meet the following requirements:

(1) Each project must have a project director who works at the grantee institution or training site institution, has relevant training and experience, and has been approved by the Secretary to direct the project.

(2) Each project must have an appropriate administrative and organizational plan and appropriate faculty, staff, and facility resources for the achievement of stated objectives.

(3) Each project must systematically evaluate the educational program including preceptors, the administration of the program, and the degree to which program and educational objectives are met.

(4) Each project, other than a faculty development project, must use amubulatory care settings where family medicine is practiced and when an adequate portion of the clinical training is conducted.

(5) Each project, other than a faculty development project, must have a family medicine curriculum which:

(i) Is appropriate for the academic level of the trainees and the specific length and nature of the educational program;

(ii) Supplements any practical (including clinical) experiences with related education activities; and

(iii) Emphasizes subjects pertinent to:

(A) Ambulatory care;

(B) Psychosocial skills and topics; and

(C) Related nonclinical areas relevant to the practitioner of family medicine.

(b) *Additional requirements for predoctoral training programs.* In addition to the requirements of paragraph (a) of this section, projects for predoctoral training programs must also meet the following additional requirements:

(1) The training program must be sponsored and supervised by an appropriate administrative unit in family medicine, the faculty of which participates in the preparation of the preclerkship curriculum and required courses and activities, for which faculty may be interdisciplinary, such as physical diagnosis and clinical pathological conferences, and which coordinates the predoctoral offering of clerkships and other clinical experiences oriented to family medicine.

(2) Each training program must be part of an integrated institutional strategy to provide education and training in family medicine designed to encourage an appropriate percentage of its graduates, annually, to seek graduate training in family medicine and eventually to enter a career in family medicine.

(3) For projects which include preceptorships in family medicine:

(i) The project must provide medical or osteopathic students with ambulatory care training in a community setting.

(ii) Preceptors must have practices which are consistent with the principles of family medicine and must be selected by the administrative unit in family medicine.

(iii) Stipend support from grant funds may be given to trainees who are not receiving academic credit for the preceptorship only if they (A) need it; (B) indicate an interest in working in the field of family medicine; and (C) engage in the preceptorship full time for at least four consecutive weeks. Stipend support from grant funds may be given to trainees who are receiving academic credit for the preceptorship only when the three conditions above are met and, additionally, when the trainee incurs extraordinary living expenses due to participation in the preceptorship.

(4) For projects for student assistantships:

(i) A family medicine faculty member of the administrative unit, identified under paragraph (b)(1) of this section, must supervise each student assistant.

(ii) The grantee must give preference in admission to the training program to applicants considering a career in academic family medicine.

(iii) Stipend support from grant funds may be given to trainees who are not receiving academic credit for the assistantship only if they (A) need it; (B) indicate an interest in working in the field of family medicine; and (C) engage in the assistantship full time for at least eight consecutive weeks. Stipend support from grant funds may be given to trainees who are receiving academic credit for the preceptorship only when the three conditions above are met and, additionally, when the trainee incurs extraordinary living expenses due to participation in the preceptorship.

(c) *Additional requirements for graduate training projects (except faculty development).* In addition to the requirements of paragraph (a) of this section, projects for approved or accredited residency training programs must meet the following additional requirements:

(1) Each program must have a supervisor of training with appropriate experience and training who is responsible for coordination and supervision of training in the program.

(2) Each program must use an appropriate resident or intern recruitment and selection process which assures that residents and interns in the program have applied specifically for training in the approved graduate training program.

(3) Each program must provide education for a sufficient number of interns or residents to provide an adequate collegial environment for the educational program and to enhance cost efficiency.

(4) Each program must have an adequate number of qualified faculty with training and experience in family medicine, behavioral sciences, and liaison specialties, for the number of interns or resident in the program. The faculty of the program must engage in periodic educational activities to improve their teaching skills.

(5) Each program must provide an appropriate amount of clinical training for each intern or resident in ambulatory care settings emphasizing family medicine in each year of the training program. This training will be

for the purpose of assuring an adequate education in the principles of the practice of family medicine throughout the program. In addition, each training program must provide clinical training in other ambulatory care settings relevant to family medicine, such as emergency units.

(6) Each program must have adequate facilities for the provision of the educational activities and, in particular, have family medicine ambulatory care space sufficient to provide an adequate clinical experience for the interns or residents.

(7) Each intern or resident must serve a sufficient number of families and individual patients with a variety of health care needs to provide the resident with a broad clinical experience.

(d) *Additional requirements for faculty development programs.* (1) Each project must have a curriculum which:

(i) Directly applies to family medicine training programs;

(ii) Emphasizes improvement of pedagogical skills for clinical and classroom settings; and

(iii) Uses didactic and nondidactic teaching strategies.

(2) Only physicians who teach or intend to teach in family medicine are eligible to participate as trainees in the program.

(3) Each program must have a sufficient number of trainees participating during the conduct of any educational activities to provide a collegial environment and to make the program cost efficient.

(4) Each program must be no longer than 1 calendar year for any trainee.

(5) To be eligible for financial assistance from grant funds, a trainee must:

(i) Intend to teach in family medicine training program on a full-time basis; and

(ii) Be a full-time participant in the training program for at least three months.

§ 57.1605 How will applications be evaluated?

(a) After consultation with the National Advisory Council on Health Professions Education established by section 702 of the Act, the Secretary will approve projects which best promote the purposes of section 786(a) of the Act. The Secretary will consider, among other factors:

(1) The degree to which the proposed project provides for the project requirements in § 57.1605;

(2) The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner; and

(3) The potential of the project to continue on a self-sustaining basis.

(b) In determining the priority for funding, projects approved under paragraph (a) of this section, the Secretary will consider:

(1) The relative merit of the proposed project based upon the factors in paragraph (a) of this section; and

(2) The extent to which a proposed project contains any of the following elements:

(i) For all projects except faculty development projects, substantial training experience in settings which exemplify interdependent utilization of physicians and physician assistants or nurse practitioners.

(ii) For all projects except faculty development projects, substantial portions of the training program are conducted in a health manpower shortage area(s) designated under section 332 of the Act, or in an area health education center funded, at least in part, under section 781 of the Act.

(iii) For faculty development projects, emphasis on increasing the number of new faculty who will be teaching on a full-time basis in family medicine.

§ 57.1606 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 5 years.

(b) Generally, the grant will initially be funded for one year, and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

(d) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 57.1607 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

§ 57.1608 What health planning requirements must benefit?

A grant may be made under this subpart only if the applicable requirements of Title XV of the Act relating to review approval by the appropriate health systems agency have been met.

§ 57.1609 What additional Department regulations apply to grantees?

Several other regulations apply to these grants. They include, but are not limited to:

42 CFR Part 50—PHS grant appeals process.
45 CFR Part 16—Department grant appeals process.
45 CFR Part 46—Protection of human subjects.
45 CFR Part 74—Administration of grants.
45 CFR Part 75—Informal grant appeals procedures (indirect cost rates and other cost allocations).
45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance from the Department—Implements Title VI of the Civil Rights Act of 1964.
45 CFR Part 81—Practice and procedure for hearings under Part 80.
45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs.
45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.
45 CFR Part 86—Nondiscrimination on the basis of sex in Federally assisted education programs.
45 CFR Part 91 [1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance.

§ 57.1610 What other audit and inspection requirements apply to grantees?

Each school which receives a grant under this subpart must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act, concerning audit and inspection.

§ 57.1611 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of an award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

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[1] When issued.

Subpart R—[Reserved]

Subpart S—Educational Assistance to Individuals from Disadvantaged Backgrounds

AUTHORITY: Sec. 215, Public health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 316); secs. 787 and 798 of the Public Health Service Act, 90 Stat. 2309, 2313 (42 U.S.C. 295g-7; 42 U.S.C. 295h-7).

SOURCE: 45 FR 73052, Nov. 4, 1980, unless otherwise noted.

§ 57.1801 To what grant program do these regulations apply?

These regulations apply to grants to eligible schools and entities under sections 787 and 798 of the Public Health Service Act to assist individuals from disadvantaged backgrounds to enter and graduate from health professions schools or from programs providing education in the allied health professions.

§ 57.1802 Definitions

"Act" means the Public Health Service Act, as amended.

"Allied health professions" means professions which support, complement, or supplement the professional functions of physicians, dentists, and other health professionals in the delivery of health care to patients, or assist environmental engineers and other personnel in environmental health control and preventive medicine activities.

"Health professions" means the professions of medicine, dentistry, osteopathy, pharmacy, optometry, veterinary medicine, podiatry, and public health.

"Health professions schools" means schools of medicine, dentistry, osteopathy, pharmacy, optometry, veterinary medicine, podiatry, or public health as they are defined in section 701(4) of the Act.

"National of the United States" (as defined in 8 U.S.C. 1101(a)(22), the Immigration and Nationality Act) means a citizen of the United States or a person who, though not a citizen of the United States, owes permanent allegiance to the United States.

"Nonprofit" as applied to any private entity means none of its net earnings may lawfully benefit any private shareholder or individual.

"School of allied health" means a school which provides training in the allied health professions as one of its major functions.

"Secretary" means the Secretary of Health and Human Services or any officer or employee of the Department to whom the authority involved has been delegated.

"State" means in addition to the several states, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

§ 57.1803 Who is eligible to apply for a grant?

(a) Health professions schools, schools of allied health, and public or nonprofit private health or educational entities which provide health or educational programs as one of their major functions may apply for grants under section 787 or 798 of the Act. The school or entity must be located in a State.

(b) Applicants which offer degree programs in the allied health professions must meet relevant standards and guidelines established by appropriate:

(1) Accrediting bodies recognized by the Secretary of Education, or

(2) Federal or State agencies.

§ 57.1804 Who is eligible for educational assistance?

To be eligible for educational assistance under this program, an individual must:

(a) Be a national of the United States or a permanent resident of the Trust Territory of the Pacific Islands or the Northern Mariana Islands, or a lawful permanent resident of the United States, Puerto Rico, the Virgin Islands, or Guam; and

(b) Come from a disadvantaged background. For this program, an individual from a disadvantaged background is one who:

(1) Comes from an environment that has inhibited the individual from obtaining the knowledge, skill, and abili-

ties required to enroll in and graduate from a health professions school, or from a program providing education or training in an allied health profession; or

(2) Comes from a family with an annual income below a level based on low income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and adjusted by the Secretary for use in all health professions programs. The Secretary will periodically publish these income levels in the FEDERAL REGISTER.

For grants under section 798 of the Act, veterans of the Armed Forces with military training or experience in the health field are considered individuals from disadvantaged backgrounds.

§ 57.1805 Program requirements.

(a) The Secretary will award grants to meet the cost of carrying out one or more of the following five purposes:

(1) To identify individuals from disadvantaged backgrounds for education in the health or allied health professions through the development and application of criteria for this purpose, and to recruit these individuals through motivational activities which may involve dissemination of information, exposure to role models and health facilities, and counseling.

(2) To provide individuals from disadvantaged backgrounds with preliminary education in a health professions school or school of allied health, or to refer them to institutions which provide it. Preliminary education in this context is education designed to assist individuals from disadvantaged backgrounds to complete the regular course of education in a health professions school or school of allied health. It may not include classes already taught as part of the regular course of education leading to a high school diploma or undergraduate degree. It may not be offered to students before they complete the junior year of high school.

(3) To provide information to individuals from disadvantaged backgrounds about financial aid available to students in health professions schools, or schools of allied health, or schools and entities which provide training necessary to qualify for enrollment in health professions schools or schools of allied health.

(4) To facilitate the entry of individuals from disadvantaged backgrounds into health professions schools or schools of allied health by engaging in activities which assist them to compete for admission, such as instruction designed to improve their performance on admission tests, and by assisting admission committees with the evaluation of disadvantaged applicants.

(5) To provide counseling or other retention services, such as tutorial assistance and assistance in adjusting to the environment of the school, which are designed to help individuals from disadvantaged backgrounds who are enrolled in health professions schools or schools of allied health to complete this education. Although it is allowable for a grantee to receive funding for only one of these purposes, its program must carry out at least two of them.

(b) The grantee must evaluate its program based on the plan provided in the grant application.

§ 57.1806 How will applications be evaluated?

After consulting with the National Advisory Council on Health Professions Education established under section 702 of the Act, the Secretary will decide which applications to approve by considering, among other factors:

(a) The degree to which the proposed project adequately provides for the requirements in § 57.1805;

(b) The number and types of individuals who can be expected to benefit from the project;

(c) The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner;

(d) The adequacy of the staff and faculty;

(e) The soundness of the budget; and

(f) The potential of the project to continue without further support under this program.

Within the limits of funds available, the Secretary will award grants to approved applicants with projects that will best promote the purposes of sections 787 and 798 of the Act.

§ 57.1807 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed three years.

(b) Generally, the grant will initially be funded for one year, and subsequent continuation awards will also be funded for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of factors such as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

(d) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 57.1808 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations.

(b) The grantee may not spend grant funds to:

(1) Pay tuition or fees;

(2) Train program staff; or

(3) Retrain health professionals.

(c) The grantee may spend grant funds with the Secretary's prior approval to provide one round trip for each individual in the program between his or her residence and the training site if:

(1) The training site is beyond a reasonable commuting distance and requires the individual to establish a temporary new residence; and

(2) The educational assistance is not offered at a time when the individual would be at the training site anyway as a student in a regular course of education leading to a high school diploma, undergraduate degree, or degree in the health or allied health professions.

(d) The grantee may spend grant funds with the Secretary's prior approval to pay individuals in the program a per diem up to a maximum daily amount established by the Secretary when the grantee determines that:

(1) The conditions in both paragraphs (c) (1) and (2) of this section exist;

(2) No other Federal financial assistance program is authorized to provide this support; and

(3) The individual needs this support to participate in the program.

(e) The grantee may not spend grant funds for sectarian instruction or for any religious purpose.

§ 57.1809 What additional Department regulations apply to grantees?

Several other Department regulations apply to grantees. They include, but are not limited to:

45 CFR Part 50	PHS grant appeals process.
45 CFR Part 16	Department grant appeals process.
45 CFR Part 46	Protection of human subjects.
45 CFR Part 74	Administration of grants.
45 CFR Part 75	Informal grant appeals procedures (indirect cost rates and other cost allocations).
45 CFR Part 80	Nondiscrimination under program receiving Federal assistance from the Department—Implements Title VI of the Civil Rights Act of 1964.
45 CFR Part 81	Practice and procedure for hearings under Part 80.
45 CFR Part 83	Nondiscrimination on the basis of sex in the admission of individuals to training programs.
45 CFR Part 84	Nondiscrimination on the basis of handicap in federally assisted programs.
45 CFR Part 86	Nondiscrimination on the basis of sex in federally assisted education programs.
45 CFR Part 91 [1]	Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance.

[1] When issued.

§ 57.1810 What other audit and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act concerning audit and inspection.

§ 57.1811 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of any award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart T—Nursing Special Project Grants

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 820, 89 Stat. 359 (42 U.S.C. 296k).

SOURCE: 43 FR 27956, June 27, 1978, unless otherwise noted.

§ 57.1901 Applicability.

The regulations of this subpart are applicable to the award of grants to public and nonprofit private schools of nursing and other public or nonprofit private entities under section 820 of the Public Health Service Act (42 U.S.C. 296k) to assist in meeting the costs of special projects.

§ 57.1902 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"Council" means the National Advisory council on Nurse Training established by section 851(a) of the Act.

"Budget Period" means the interval of time into which the project period is divided for budgetary and reporting purposes, as specified in the grant award document.

"Project period" means the total time for which support for a project has been approved, including any extensions thereof.

"Project director" means an individual designated by the grantee in the grant application and approved by the Secretary to direct the project being supported under this subpart.

"State," except as otherwise provided herein, means a State, Puerto Rico, the District of Columbia, the Canal Zone, Guam, American Samoa, the Virgin Islands, or the Trust Territory of the Pacific Islands.

"School of nursing" means a collegiate, associate degree or diploma school of nursing, as such are defined in section 853 of the Act.

"Nonprofit" as applied to any school or entity means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inure or may lawfully inure to the benefit of any private shareholder or individual.

"Nursing personnel who are billingual" means nursing personnel with the ability to speak and understand, in addition to English, a language used by any major United States population group composed of individuals of limited English-speaking ability.

"Individuals of limited English-speaking ability" means: (1) individuals who were not born in the United States or whose native language is a language other than English, and (2) individuals who come from environments where a language other than English is dominant, and by reason thereof, have difficulty speaking and understanding the English language.

§ 57.1903 Eligibility.

(a) *Eligible applicants.* Any public or nonprofit private school of nursing or other public or nonprofit private entity located in a State may apply for a grant under this subpart.

(b) *Eligible projects.* Grants under this subpart may be made to eligible applicants to meet the costs of special projects to carry out one or more of the following purposes:

(1) To assist in—

(i) Mergers between hospital training programs or between hospital training programs and academic institutions, or

(ii) Other cooperative arrangements among hospitals and academic institutions leading to the establishment of nurse training programs;

(2) To plan, develop, or establish new nurse training programs or programs of research in nursing education, or to significantly improve curricula of schools of nursing (including curriculums of pediatric nursing and geriatric nursing) or modify existing programs of nursing education;

(3) To increase nursing education opportunities for individuals from disadvantaged backgrounds, as determined in accordance with the criteria prescribed in § 57.1905(c), by—

(i) Identifying, recruiting, and selecting such individuals,

(ii) Facilitating the entry of such individuals into schools of nursing,

(iii) Providing counseling or other services designed to assist such individuals to complete successfully their nursing education,

(iv) Providing, for a period prior to the entry of such individuals into the regular course of education at a school of nursing, preliminary education designed to assist them to complete successfully such regular course of education,

(v) Paying such stipends as the Secretary may determine for such individuals for any period of nursing education, and

(vi) Publicizing, especially to licensed vocational or practical nurses, existing sources of financial aid available to persons enrolled in schools of nursing or who are undertaking training necessary to qualify them to enroll in such schools;

(4) To provide continuing education for nurses;

(5) To provide appropriate retraining opportunities for nurses who (after periods of professional inactivity) desire again actively to engage in the nursing profession;

(6) To help to increase the supply or improve the distribution by geographic area or by specialty group of adequately trained nursing personnel (including nursing personnel who are bilingual) needed to meet the health needs of the Nation, including the need to increase the availability of personal health services and the need to promote preventive health care;

(7) To provide training and education to upgrade the skills of licensed vocational or practical nurses, nursing assistants, and other paraprofessional nursing personnel; or

(8) To assist in meeting the costs of developing short-term (not to exceed 6 months) in-service training programs for nurses aides and orderlies for nursing homes, which programs emphasize the special problems of geriatric patients and include training for monitoring the well-being and feeding and cleaning of the patients in nursing homes, selected emergency procedures, basic knowledge of drug properties and interactions, and fire safety techniques.

§ 57.1904 Application.

(a) Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at the time as the Secretary may prescribe.[1]

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[1] Applications and instructions may be obtained from the Division of Nursing, Bureau of Health Manpower, Health Resources Administration, Department of Health and Human Services, Center Building, Room 3-50, 3700 East-West Highway, Hyattsville, Md. 20782.

(b) The application shall be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations of this subpart.

(c) In addition to such other pertinent information as the Secretary may require, an application for a grant under this subpart shall contain the following:

(1) A proposal for a project to carry out one or more of the purposes specified in § 57.1903(b).

(2) Information documenting the need for the proposed project.

(3) A description of the anticipated impact of the proposed project, including its potential contribution to nursing.

(4) A detailed plan for achieving and measuring the stated objectives of the proposed project.

(5) A description of the resources available for the conduct of the proposed project, including faculty, staff, equipment, facilities, and, where applicable, a clinical practice setting or settings.

(6) A detailed budget for the proposed project and a justification of the amount of grant funds requested.

(7) A description of any Federal financial support related to the proposed project which the applicant is currently receiving.

(8) A detailed timetable for carrying out the activities of the proposed project, including any plans for continuing such activities beyond the project period.

(9) A description of the background and qualifications of the project staff and any proposed consultants.

(10) A description of any written agreements with other institutions or organizations for carrying out the proposed project.

(11) If the proposed project includes the provision of training, information concerning the source and number of potential students and a description of recruitment plans and criteria for the selection and admission of students.

§ 57.1905 Project requirements.

A project supported under this subpart shall be conducted in accordance with the following requirements:

(a) The project shall be conducted under the direction of the project director. If the project director becomes unable to function in such capacity, the Secretary shall be notified as soon as possible.

(b) If the project is designed to carry out the purpose of § 57.1903(b)(2)(i), the new nurse training program or program of research in nursing education to be planned, developed, or established shall be operational within the project period.

(c) If the project is designed to carry out the purpose of § 57.1903(b)(3), the grantee may consider an individual to be from a disadvantaged background if the individual:

(1) Comes from an environment that has inhibited the individual from obtaining the knowledge, skills, and abilities required to enroll in and graduate from a school of nursing; or

(2) Comes from a family with an annual income below a level based on low-income thresholds by family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and multiplied by a factor to be determined by the Secretary for adaptation to this program. The Secretary periodically will publish in the FEDERAL REGISTER the income levels as adjusted.

(d) If the project is designed to carry out the purpose of § 57.1903(b)(4), the project shall provide a continuing education program which: (1) is designed to have wide applicability for the nursing profession, and (2) has an enrollment not limited to nurses employed by a single institution.

(e) If the project is designed to carry out the purpose of § 57.1903(b)(5), the project shall provide a retraining program which: (1) has a curriculum that includes classroom instruction and faculty-supervised clinical training, (2) is designed to have wide applicability for the nursing profession, and (3) has an enrollment not limited to nurses employed by a single institution.

(f) If the project is designed to carry out the purpose of § 57.1903(b)(7), the project shall provide a training program which: (1) is designed to have wide applicability for the nursing field, and (2) has an enrollment not limited to nurses employed by a single institution.

(g) If the project is designed to carry out the purpose of § 57.1903(b)(8), the project shall develop a training program for nursing home personnel, the curriculum, course materials, and methodology of which can be used on a regional, State or national basis.

§ 57.1906 Evaluation and grant award.

(a) *Evaluation.* (1) Within the limits of funds available for this purpose, the Secretary, after consultation with the Council, may award grants to those applicants whose projects will, in his or her judgment, best promote the purposes of section 820 of the Act, taking into consideration among other pertinent factors:

(i) The national or special local need which the particular project proposes to serve;

(ii) The potential effectiveness of the proposed project in carrying out such purposes;

(iii) The administrative and managerial capability of the applicant to carry out the proposed project;

(iv) The adequacy of the facilities and resources available to the applicant to carry out the proposed project;

(v) The qualifications of the project director and proposed staff;

(vi) The reasonableness of the proposed budget in relation to the proposed project; and

(vii) The potential of the project to continue on a self-sustaining basis after the period of grant support.

(b) *Grant awards.* (1) The amount of any award will be determined by the Secretary on the basis of his or her estimate of the sum necessary for all or a designated portion of the direct costs of the project plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (i) on the basis of his or her estimate of the actual indirect costs reasonably related to the project, or (ii) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of this percentage will not exceed the approximate actual indirect costs. This award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limit of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(2) All grant awards shall be in writing and shall set forth the amount of funds granted and the period for which funds will be available for obligation by the grantee. Projects receiving grants under this subpart may be approved for an initial project period of up to three years. Grantees may apply for up to two years of additional support by submitting a competing extension application.

(3) Neither the approval of any project nor the award of any grant shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees shall make separate application in a form and at the time that the Secretary may prescribe.

(c) *Noncompeting continuation awards.* If a grantee has filed an application for continuation support, the Secretary may make a grant award, within the limits of funds available for this purpose, for an additional budget period for any previously approved project on the basis of progress and accounting records which the Secretary may require, if the application is for a project which meets the regulations of this subpart. If the Secretary finds that the project's activities during the current budget period justify continued support of the project for an additional budget period, and the Secretary decides to continue support, the amount of the grant award will be determined in accordance with paragraph (b)(1) of this section. If the Secretary decides not to continue supporting a project for an additional budget period, he or she will notify the grantee in writing before the end of the current budget period. In addition, the

Secretary may provide financial support for the orderly phaseout of the supported project, if he or she determines that this support is necessary.

§ 57.1907 Grant payments.

The Secretary will from time to time make payments to the grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the budget period, or in advance for expenses to be incurred, to the extent he or she determines these payments necessary to promote prompt initiation and advancement of the approved project.

§ 57.1908 Expenditure of grant funds.

(a) Any funds granted pursuant to this subpart shall be expended solely for carrying out the approved project in accordance with section 820 of the Act, the regulations of this subpart, the terms and conditions of the award, except that funds may not be expended for sectarian instruction or for any religious purpose.

(b) Any unobligated grant funds remaining in the grant account at the close of a budget period may be carried forward and be available for obligation during subsequent budget periods of the project period. The amount of a subsequent award will take into consideration the amount remaining in the grant account. At the end of the last budget period of the project period, any unobligated grant funds remaining in the grant account shall be refunded to the Federal Government.

§ 57.1909 Nondiscrimination.

(a) Recipients of grants under this subpart are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations are applicable:

(1) Section 855 of the Act (42 U.S.C. 298b-2) and its implementing regulation, 45 CFR Part 83 (prohibiting discrimination on the basis of sex in the admission of individuals to training programs).

(2) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its implementing regulation, 45 CFR Part 80 (prohibiting discrimination in Federally assisted programs on the ground of race, color, or national origin).

(3) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) and its implementing regulation, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in Federally assisted education programs).

(4) Section 504 of the Rehabilitation Act of 1973, (29 U.S.C. 794) and its implementing regulation, 45 CFR Part 84 (prohibiting discrimination in Federally assisted programs on the basis of handicap).

(b) The grantee shall not discriminate on the basis of religion in the admission of individuals to its training programs.

§ 57.1910 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart. When the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of these predetermined fixed-percentage rates applied to the total or selected elements of the reimbursable direct costs incurred.

(b) *Accounting for copyright royalties.* Royalties received by grantees from copyrights on publications or other works developed under the grant shall be accounted for as follows:

(1) Royalties received during the period of grant support may be retained by the grantee and, in accordance with the terms and conditions of the grant, used in either or both of the following ways:

(i) Used by the grantee for any purposes that further the objectives of section 820 of the Act.

(ii) Deducted from the total project costs for the purpose of determining the net costs on which the Federal share of costs will be based.

(2) Royalties received after the completion or termination of grant support may be retained by the grantee, unless the terms and conditions of the grant or a specific agreement negotiated between the Secretary and the grantee provide otherwise, except that any grantee that is a State or local government, as defined in 45 CFR 74.3, which receives royalties in excess of $200 a year must return the Federal share of the excess amount (computed by applying the percentage of Federal participation in the cost of the grant-supported project to the excess amount) to the Federal Government, unless a specific agreement provides otherwise.

(c) *Grant Closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of (i) any amount not accounted for pursuant to paragraphs (a) and (b) of this section; and (ii) any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74 and the terms and conditions of the grant award. This total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assigns by setoff or other lawful action.

§ 57.1911 Publications and copyright.

The policies of 45 CFR 74.140 shall apply to grants made under this subpart.

§ 57.1912 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in Subpart A of Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to all other grantee organizations under this subpart:

Subpart:
A General.
B Cash Depositories.
C Bonding and Insurance.
D Retention and Custodial Requirements for Records.
F Grant-Related Income.
K Grant Payment Requirements.
L Budget Revision Procedures.
M Grant Closeout, Suspension, and Termination.
O Property.
Q Cost Principles.

§ 57.1913 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his or her judgment the conditions are necessary to assure or protect advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart U—Armed Forces Health Professions Scholarship Program

AUTHORITY: Sec. 2(a), Pub. L. 92-426, 86 Stat. 719 (10 U.S.C. 2127(d)).

SOURCE: 38 FR 20447, Aug. 1, 1973, unless otherwise noted.

§ 57.2001 Applicability.

In the event the Secretary of Defense decides to enter into one or more contracts under 10 U.S.C. 2127(d), the regulations in this subpart outline considerations the Secretary of Defense will take into account in determining whether an accredited civilian educational institution has increased its total enrollment for the sole purpose of accepting members of the Armed Forces health professions scholarship program.

§ 57.2002 Definitions.

As used in this subpart:

(a) "Institution" means a college, university, or other institution or a department, division, or other administrative unit within a college, university, or other institution, which provides primarily or exclusively a course of study in medicine, dentistry, or other health profession, as determined under regulations prescribed by the Secretary of Defense, leading to a degree in one of said health professions, and which is accredited by an accrediting agency or association recognized by the United States Commissioner of Education.

(b) "Enrollment" in any fiscal year means the number of full-time students enrolled in an institution on October 15 of said year and pursuing a course of study which constitutes a full-time academic workload, as determined by the institution, leading to a degree in medicine, dentistry, or other health profession, as determined under regulations prescribed by the Secretary of Defense: *Provided*, That if the Secretary of Defense finds that a date other than October 15 would more accurately reflect an institution's enrollment in any fiscal year, the Secretary of Defense may use such other date in place of October 15 in making his determination under this subpart.

(c) "Fiscal year" means the Federal fiscal year beginning July 1 and ending on the following June 30.

(d) "Program" means the Armed Forces health professions scholarship program established under section 2(a) of the Uniformed Services Health Professions Revitalization Act of 1972 (86 Stat. 713, Pub. L. 92-426), and codified in chapter 105 of 10 U.S.C.

§ 57.2003 Determinations of increased enrollment solely for the program.

In the event the Secretary of Defense decides to enter into one or more contracts under 10 U.S.C. 2127(d), his determination as to whether an institution has increased its total enrollment in any fiscal year for the sole purpose of accepting members of the program will take into account the following considerations:

(a) A comparison of the total enrollment in said fiscal year with the total enrollments in immediately preceding fiscal years;

(b) Any increases in enrollment to which the institution has directly or indirectly committed itself in said fiscal year under: (1) Other Federal programs, such as those set forth in title VII and VIII of the Public Health Service Act (42 U.S.C. 292 et seq.), the Veterans' Administration Medical School Assistance and Health Manpower Training Act of 1972 (Pub. L. 92-541, 86 Stat. 1100 (38 U.S.C. 5070 et seq.)) and section 225 of the Public Health Service Act (sec. 5, Pub. L. 92-585, 86 Stat. 1293 (42 U.S.C. 234)); (2) programs of State or local governments or other public or private agencies, or (3) any legally binding arrangement: *Provided*, That insofar as a single increase may be applied to satisfy the commitments under two or more programs and/or other arrangements, said increase shall be considered to meet all such commitments;

(c) Any unusual factors, such as: (1) An institution having been newly established or (2) an institution experiencing what is for it an abnormal rate of attrition and/or admission.

Subpart V—Grants for Training in Emergency Medical Services

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690, as amended 63 Stat. 35 (42 U.S.C. 216); sec. 789, Public Health Service Act, 90 Stat. 2243, as amended 90 Stat. 2709 (42 U.S.C. 295g-9).

SOURCE: 45 FR 60433, Sept. 12, 1980, unless otherwise noted.

§ 57.2101 To what programs do these regulations apply?

These regulations apply to the award of grants under section 789 of the Act to schools of medicine, dentistry, osteopathy, and nursing; training centers for allied health professions; hospitals, and other appropriate educational and public entities, to assist in meeting the cost of:

(a) Training programs in the techniques and methods of providing emergency medical services; and

(b) Providing financial assistance (in the form of traineeships and fellowships) to residents who participate in projects for the residency training of emergency physicians, and who plan to specialize or work in the practice of emergency medicine.

§ 57.2102 General policy.

Grant awards will be made to eligible entities in the establishment, improvement, or expansion of training programs in the techniques and methods of providing emergency medical services, which will contribute to the establishment, operation, improvement, or expansion of emergency medical services systems.

§ 57.2103 Definitions.

"Act" means the Public Health Service Act as amended.

"Advanced Life Support Facility" or "ALS facility" means a hospital with facilities and services specifically designed for the care of critical illnesses and injuries such as trauma, including burns and spinal cord injuries, acute cardiac disorders, high risk infants, poisoning, and behavioral problems, including acute alcohol intoxication, drug overdose and psyschiatric conditions.

"Appropriate public entity" means a State, a unit of general local government, or any other public entity which:

(a) Has established an emergency medical services system; and

(b) Except with respect to the basic training of emergency medical technicians, has entered into an agreement with an appropriate education entity for a training program supported under this subpart.

"Associate advanced life support facility" or "associate ALS facility" means a health care delivery facility that interrelates in terms of area-wide advanced life support planning (including educational planning) with a designated advanced life support facility.

"Clinical experience" means direct, supervised participation in patient care by observation, examination, and performance of procedures as are appropriate for the assigned role of the trainee on the health team.

"Educational entity" means:

(a) A public or nonprofit private school of medicine, dentistry, or osteopathy as defined in section 701(4) of the Act and which is accredited under section 772(b) of the Act;

(b) A school of nursing, as defined in section 853(2) of the Act;

(c) A training center for allied health professions, as defined in section 795(2) of the Act; or

(d) A public or nonprofit private organization which has the provision of educational programs as one of its major functions and which itself delivers emergency medical services or has a written agreement with an organization which delivers these services and agrees to provide the setting for the clinical experience required for the proposed training.

"Emergency medical services" means the services used in responding to the perceived individual need for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury.

"Emergency medical services council" means a public agency or a formally established or recognized advisory body of a public agency responsible for review and evaluation of emergency medical services in the area of the project.

"Emergency medical services system" means a system which provides for the arrangement of personnel, facilities, and equipment for effective and coordinated delivery of health care services in an appropriate geographical area under emergency conditions (occurring either as a result of the patient's condition or of natural disasters or similar situations) and which is administered by a public or nonprofit private entity which has the authority and the resources to provide effective administration of the system.

"Emergency medical services systems director" means the designated person responsible for overall direction of the emergency medical services system in the geographic area of the system.

"Emergency medical technicians—paramedic" means persons trained to provide advanced life support services including trauma and cardiac care, and other critical medical prehospital care for acutely ill or injured patients (i.e., treatment of shock, drug administration, and cardiac arrhythmia detection and control).

"Emergency nursing" means:

(a) The unscheduled or episodic nursing care of individuals with acute physical or emotional illnesses which require prompt intervention, and;

(b) the administration, research, and teaching of other emergency medical services activities.

"Emergency physician" means a licensed physician who is trained to and engages in:

(a) the immediate recognition, evaluation, and care of acutely ill or injured patients under emergency conditions;

(b) The administration, research, and teaching of all aspects of emergency medical services; and

(c) the direction of the patient to sources of follow-up care in or outside the hospital, as required.

"Medical director" means an emergency physician who provides medical direction for the entire program of clinical instruction and evaluates students' clinical experience.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

"Training program director" means an individual designated to provide competent overall direction and coordination for the organization, administration, periodic review, continued development, and effectiveness of the educational program.

§ 57.2104 Who is eligible to apply for a grant?

Any educational entity, appropriate public entity, or public or nonprofit private hospital located in a State may apply for a grant.

§ 57.2105 Application contents.

In addition to other pertinent information which the Secretary may require, an application for a grant under this subpart must contain:

(a) A detailed description of the proposed project which meets the applicable requirements of § 57.2106 including:

(1) A description of the specific measurable objectives of the proposed project which are consistant with the purposes of section 789 of the Act, and a detailed plan for achieving those objectives;

(2) A description of the administrative staff and faculty available for the conduct of the proposed project, including their professional background, qualifications, academic training, responsibilities, and functions;

(3) A description of the facilities, equipment, and educational resources available for the conduct of the proposed project;

(4) A description of any cooperative arrangements with other institutions, agencies, or organizations for carrying out the proposed project, including arrangements for the provision of clinical practice facilities;

(5) A detailed description of the curriculum for the training program;

(6) A description of recruitment plans and criteria for the selection and admission of students, including the extent to which the program intends to emphasize the recruitment and necessary training of veterans of the Armed Forces with military training and experience in health care fields and of appropriate public safety personnel, which include policemen, fire fighters, and other public employees charged with maintaining public safety;

(7) An estimate of the number of individuals to be trained in each training cycle;

(8) A detailed budget for the proposed project and a justification of the amount of grant funds requested;

(9) A description of the financial resources available to the applicant to assure the sound establishment and maintenance of the proposed project, including a description of the extent to which funds have either been sought by or have been made available to the applicant from Federal programs authorized by statutes other than the Act for the support of the proposed project; and

(10) A description of the plans, if any, for continuing the proposed project beyond the project period.

(b) Evidence of the unavailability of educational programs necessary to supply and maintain sufficient numbers of emergency physicians, dentists, nurses, allied health personnel, and emergency medical technicians (ambulance and paramedic) needed to provide emergency health services on a 24-hour basis in the geographic area for which the applicant proposes to train personnel.

(c) Evidence that the proposed project is coordinated with other programs (existing or planned) in the geographic area for which the applicant proposes to train emergency medical personnel.

(d) Evidence that all applicable requirements of section 1513(e) of the Act have been met.

(e) Evidence that the proposed project has been submitted for review to the emergency medical services system director, the emergency medical services council, if any, and any other entities responsible for the review of emergency medical services in the geographic area for which the applicant proposes to train emergency medical personnel. Copies of any written comments received from these reviews must be submitted to the Secretary.

(f) If stipend support is requested by an applicant to provide a portion of the salary of residents enrolled in the program, documentation showing that income available from alternative sources, including income derived from the services of the residents in the program, will be insufficient to pay their salaries and that grant funds will not be used to supplant other available funds.

§ 57.2106 Project requirements.

(a) *General requirements.* A project supported under this subpart must be conducted in accordance with the following requirements:

(1) The project must be conducted in accordance with section 789 of the Act, the regulations of this subpart, the approved application, and the terms of the award.

(2) The project must provide a training program which meets relevant standards and guidelines established by appropriate:

(i) Accrediting bodies recognized by the Secretary of Education,

(ii) Federal or State agencies, or

(iii) Professional associations;

unless the Secretary determines for demonstration purposes that the requirement of this paragraph should be waived on an application by application basis.

(3) The project must provide the training necessary to enable its graduates to meet any relevant laws or regulations governing employment standards or credentials for emergency medical personnel in the geographic area for which the applicant proposes to train personnel.

(4) The project must have a systematic plan for evaluating the training program, inclusing the performance of the students, the degree to which defined objectives are met, and the impact of the program on the delivery of emergency medical services in the geographic area for which the project proposes to train emergency medical personnel.

(5) The project must have an appropriate setting for the clinical experience required for the training which must be provided either by the grantee or through a written agreement with an organization delivering emergency medical services. The facility chosen for the clinical experience must have major emergency medical capabilities and adequate patient volume and must deliver a variety of emergency medical services.

(6) The project must have available adequate faculty, staff facilities, and equipment for the conduct of the training program.

(7) The project must have a grant project director. The grant project director may also be a training program director. If the grant project director becomes unable to function in this capacity, the Secretary must be notified as soon as possible.

(8) The project must have a training program director who:

(i) Supervises (A) the processing of student applications and the selection of students, (B) the maintenance of a complete inventory of all training equipment available to the program, and (C) the scheduling of classes and assignment of instructors, insuring that the required equipment and materials are available at each class;

(ii) Assists in instruction, as appropriate, and in the coordination of the examination and evaluation of students, including the preparation of assessment materials;

(iii) Counsels students on an individual basis;

(iv) Serves as liaison between students, program staff, and the sponsoring institution and its affiliates; and

(v) Prepares the program budget.

(9) The project must establish and use uniform student selection criteria.

(10) The project must maintain a record of the participation in the program and the level of competence attained by each student.

(11) The grantee must provide the students with a statement of satisfactory completion of the course.

(b) *Specific requirements.* In addition to the requirements of paragraph (a) of this section, projects for the training of emergency medical technicians (ambulance and paramedic), emergency nursing personnel, or emergency physicians must also meet the following specific requirements, as appropriate:

(1) *Projects for the training of emergency medical technicians-ambulance.* The project must either:

(i) Meet the guidelines prescribed by the "Basic Training Course for Emergency Medical Technicians" (Second Edition) 1977, U.S. Department of Transportation, NHTSA, which is incorporated by reference and made a part of these regulations. Copies of this document may be obtained from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402; or

(ii) Demonstrate that at least 75 percent of the graduates of the program either pass the National Registry of Emergency Technicians Examination within six months after graduation or meet applicable State requirements which are determined by the Secretary to equal or exceed Department of Transportation guidelines.

(2) *Projects for the training of emergency medical technicians-paramedic.* (i) The training program must prepare students to meet the performance standards contained in Appendix A of the "National Training Course Guide for Emergency Medical Technicians-Paramedic," which is referred to in these regulations as the "Course Guide," developed by the Department of Transportation's National Highway Traffic Safety Administration, which is hereby incorporated by reference and made a part of these regulations. Copies of this document (Stock Number 050 003 00279-8) may be obtained from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, at the cost of $2.50.

(ii) The course goals by module and course content of the training program must conform to those outlined in Appendices B and C of the Course Guide.

(iii) The clinical experience must be based at a school of medicine or osteopathy, hospital or other health care delivery facility which can assure sufficient medical supervision and clinical experience as set forth in the Course Guide. A substantial portion of this experience must be in as ALS facility or in an associate ALS facility which has appropriate resources.

(iv) Only individuals who have a high school diploma or equivalent degree may be enrolled in the training program.

(v) The project must have a medical director. The medical director may be the training program director.

(vi) The project must provide for the continuing education of the faculty in content areas related to their educational responsibilities.

(3) *Projects for the training of emergency nursing personnel.* (i) The project must prepare nurses to meet the "Standards of Emergency Nursing Practice" developed by the American Nurses' Association and the Emergency Department Nurses' Association (ANA Publication Code MS-5), or equivalent standards as determined by the Secretary. This document is hereby incorporated by reference and made a part of these regulations. Copies can be obtained from the Emergency Department Nurses' Association, 666 North Lake Shore Drive, Chicago, Illinois 60611.

(ii) The training program director must be a registered nurse with education in emergency patient care, at least one year of experience in emergency services, and with experience in baccalaureate nursing education.

(iii) The project must have a medical advisor who is an emergency physician and will advise the training program director regarding medical control and supervision in the clinical environment.

(iv) Only individuals who are licensed registered nurses or are full-time students in a school of nursing and have completed courses in basic patient care, maternal and child health, mental health and medical-surgical nursing may be enrolled.

(4) *Projects for the residency training of emergency physicians.* (i) The training program must be a graduate medical education program in emergency medicine which is either approved or provisionally approved by the American Osteopathic Association or is endorsed or provisionally endorsed by, or has a letter granting permission to recruit residents, from the Liaison Residency Endorsement Committee in Emergency Medicine.

(ii) The training program must provide training designed to familiarize the resident with:

(A) The functions of an emergency medical services system as listed in section 1206(b)(4)(C) of the Act;

(B) The interaction among the organizations and agencies which deliver emergency health services; and

(C) The management and organization of an emergency unit.

(iii) The grantee must sponsor at least two other types of approved graduate medical education programs (e.g., internal medicine, general surgery, or family practice).

(iv) The training program may be up to three years in length, but no less than two years. In the case of a three-year program, the first year must include general clinical experience. The last two years must include increased training and responsibilities in the emergency department with the resident assigned to other specialties to learn specific skills applicable to emergency care.

(v) The training program must be conducted in an emergency unit which is organized as a major service within an ALS or associate ALS facility.

(vi) The project must have a medical director who works full-time in an emergency unit.

(vii) The project must have a training program director. The training program director may also be the medical director.

(viii) The project must provide for the continuing education of the faculty in content areas related to their educational responsibilities.

(ix) The grantee may give stipends from grant funds only to residents who plan to specialize or work in the practice of emergency medicine.

(5) *Projects for the continuing education of physicians.* (i) Only individuals who are emergency physicians or physicians actively involved in an emergency medical services system may be enrolled.

(ii) Training must fulfill the requirements for continuing medical education credit of the American Osteopathic Association or meet Category 3 requirements of either the Liaison Committee on Continuing Medical Education or the American Medical Association.

§ 57.2107 How will applications be evaluated?

(a) After consultation with the National Advisory Council on Health Professions Education established by section 702 of the Act, the Secretary will approve projects which best promote the training purposes of section 789 of the Act. The Secretary will take into consideration among other factors:

(1) The degree to which the proposed project adequately provides for meeting the requirements in § 57.2106.

(2) The administrative and managerial capability of the applicant to carry out the proposed project.

(3) The local and national needs which the proposed project is designed to serve.

(4) The soundness of the fiscal plan for assuring effective utilization of grant funds.

(5) The potential of the project to continue on a self-sustaining basis after the project period.

(b) In determining the priority for funding of applications approved under paragraph (a) of this section, the Secretary will consider:

(1) The relative merit of the proposed project based upon the factors in paragraph (a) of this section; and

(2) The extent to which the proposed project contains any of the following elements:

(i) All training programs in the proposed project provide clinical experience in emergency medical services systems receiving assistance under Title XII of the Act.

(ii) All training programs in the proposed project emphasize interdisciplinary approaches to emergency medical services.

(iii) In the case of projects for the training of emergency medical technicians-paramedic, the proposed project is sponsored by an educational entity which grants academic credit for the training.

(iv) In the case of projects for the training of emergency physicians, the project is designed to train emergency physicians while developing general emergency physician training resources. To meet this requirement, the applicant must:

(A) Be, or be affiliated with, a school of medicine, or osteopathy with an administrative unit which is responsible for educational programs in emergency medicine, propose educational programs designed to improve the capabilities of physicians to provide emergency medical services in emergency medical services system; and

(B) Be involved in more than one of the following phases of emergency medical education: undergraduate, graduate or continuing education.

§ 57.2108 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed five years.

(b) Generally, the grant will initially be funded for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

(d) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by with withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 57.2109 How is the amount of the grant award determined?

The Secretary will determine the amount of the award to the grantee on the basis of his or her estimate of the sum necessary during the budget period to cover the costs of the project. In addition, in determining the amount of stipend support to be made available to residents who plan to specialize or work in the practice of emergency medicine, the amount of any stipend must be limited to that portion of the annual amount normally paid to other residents by the applicant which the Secretary determines, on the basis of the documentation required in the application, cannot reasonbly be paid from other available funds, including the incomes derived from the residents' services.

§ 57.2110 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under the subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

§ 57.2111 What health planning requirements must be met?

A grant may be made under this subpart only if the applicable requirements of Title XV of the Act relating to review and approval by the appropriate health systems agency have been met.

§ 57.2112 What additional Department regulations apply to grantees?

Several other regulations apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50—PHS grant appeals process

45 CFR Part 16—Department grant appeals process

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates and other cost allocations)

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance from HHS—Implements Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs

45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally-assisted education programs

45 CFR Part 86—Nondiscrimination on the basis of sex in Federally-assisted education programs

45 CFR Part 91[1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance

§ 57.2113 What other audit and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act concerning audit and inspection.

§ 57.2114 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of any award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart W—Physician Shortage Area Scholarship Grants

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216).

SOURCE: 39 FR 28730, Aug. 9, 1974, unless otherwise noted.

§ 57.2201 Applicability.

The regulations of this subpart are applicable to scholarship grants awarded under section 784 of the Public Health Service Act, which authorizes the Secretary to award scholarship grants to students of medicine and osteopathy who agree to engage in the full-time practice of primary care for a prescribed period of time (a) in a physician shortage area or (b) in such manner as to assure that of the patients receiving medical care in such practice a substantial portion will consist of migratory agricultural workers or members of their families.

§ 57.2202 Definitions.

As used in this subpart, the following terms shall have the following meanings:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

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[1] When issued.

(c) "School" means a public or other nonprofit school of medicine or osteopathy which provides a course of study, or a portion thereof, which leads respectively to a degree of Doctor of Medicine or Doctor of Osteopathy and which is accredited as provided in section 721(b)(1)(B) of the Act.

(d) "Scholarship grant" means the amount of money awarded to an individual by the Secretary for an academic year pursuant to section 784(a) of the Act.

(e) "Full-time student" means a student who is enrolled, or accepted for enrollment, in a school and pursuing a course of study which constitutes a full-time academic workload, as determined by the school, leading to a degree specified in paragraph (c) of this section.

(f) "Academic year" means the traditional, approximately 9-month September to June annual session. For the purpose of computing academic year equivalents for students who, during a 12-month period, attend for a longer period than the traditional academic year, the academic year will be considered to be of 9 months' duration.

(g) "National of the United States" means (1) a citizen of the United States or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States (8 U.S.C. 1101(a)(22)).

(h) "Professional training" means the course of study leading to the degree of doctor of medicine or doctor of osteopathy, plus a period, not to exceed a total of four years, of internship and residency training.

(i) "Low-income background" as applied to any individual means that the individual comes from a family with an annual income below low-income levels developed pursuant to § 57.605(c).

(j) "The practice of primary care" means the provision of health services characterized by the delivery of first contact medicine, the assumption of longitudinal responsibility for the patient regardless of the presence or absence of disease, and the integration of the physical, psychological and social aspects of health care to the limits of the capability of the practitioner. For purposes of this section, primary care shall include the fields of general practice, family practice, general internal medicine, general pediatrics, and general obstetrics and gynecology.

(k) "Migratory agricultural worker" means a domestic agricultural migratory worker as defined in § 56.102(d).

(l) "Physician shortage area" means an area designated by the Secretary pursuant to § 57.216(a)(5) as an area having a need for and shortage of physicians.

§ 57.2203 Eligibility.

To be eligible for a scholarship grant under this subpart, the applicant must:

(a) Be a national of the United States or a permanent resident of the Trust Territory of the Pacific Islands or a lawful permanent resident of the United States, Puerto Rico, the Virgin Islands or Guam;

(b) Be a full-time student in a school located in the United States, the Trust Territory of the Pacific Islands, Puerto Rico, the Virgin Islands, the Canal Zone, American Samoa or Guam; and

(c) Agree to engage in the full-time practice of primary care as defined in § 57.2202(j) in accord with conditions specified in § 57.2209.

§ 57.2204 Application.

Each eligible applicant desiring a scholarship grant under this subpart shall submit an application at such time and in such form as the Secretary may prescribe.

§ 57.2205 Priority for selection of scholarship recipients.

(a) When funds determined by the Secretary to be available for scholarship grants under this subpart are insufficient to permit the awarding of scholarships to all individuals applying therefor, the Secretary shall accord priority to eligible applicants as follows:

(1) First priority for scholarship grants shall be accorded to applicants who (i) are from a low-income background as defined in § 57.2202 (i), (ii) reside in a physician shortage area and

(iii) agree to return to such area and engage in the full-time practice of primary care. For purposes of this paragraph, an individual resides in a physician shortage area if he presently is residing in such an area or if he (or his parents) resided in such an area in the year prior to his admission to an institution of higher education.

(2) Second priority shall be accorded to applicants meeting the criteria in paragraph (a)(1) (ii) and (iii) of this section.

(3) Third priority shall be accorded to applicants meeting the criterion in paragraph (a)(1)(i) of this section.

(4) Fourth priority shall be accorded to other applicants.

(b) Where there are insufficient funds available to make scholarship grants to all members of any single priority grouping enumerated in paragraph (a) of this section, the following criteria will be used to accord priority within each affected priority group:

(1) Within the priority groupings specified in paragraphs (a) (1) and (2) of this section, the Secretary shall rank recipients according to the degree of the severity of shortage of physicians practicing primary care in such area. Scholarship grants shall be awarded within each priority group first to applicants within that grouping from physician shortage areas with the least favorable ratio of such physicians to the population to be served.

(2) Within the priority groupings specified in paragraphs (a) (3) and (4) of this section, the Secretary shall award scholarship grants within each priority group first to applicants who agree to practice primary care in a physician shortage area with a substantial portion of migratory agricultural workers in such area; second, to applicants within that grouping who agree to practice in a physician shortage area; and third, to applicants within that grouping who agree to practice in such place or places, facility or facilities, and in such manner as the Secretary finds necessary to assure that, of the patients receiving medical care in such practice, a substantial portion will consist of persons who are migratory agricultural workers or members of their families.

§ 57.2206 Grant award.

The Secretary may award scholarship grants to individuals who have been selected to receive scholarship grants in accordance with § 57.2205. Any such award under this subpart shall state the specific conditions under which the award is being made and shall indicate the distribution between funds awarded to cover the costs of tuition and fees payable to the school and funds awarded for the costs of equipment, supplies, books, and living expenses payable to the individual.

§ 57.2207 Amount of scholarship grant.

(a) The amount of the scholarship grant to any student for any academic year shall be the total of (1) the lesser of (i) $5,000 or (ii) the amount determined by the Secretary to be the cost of tuition and fees; plus (2) an allowance for equipment, supplies, books and living expenses which shall be the lesser of (i) $3,600 or (ii) the difference between $5,000 and the amount determined pursuant to paragraph (a)(1) of this section.

(b) The maximum amount of a scholarship grant during a 12-month period to any student enrolled in a school which provides a course of study longer than the traditional 9-month academic year may be proportionately increased.

§ 57.2208 Payment of scholarship grant.

The portion of a scholarship grant awarded for the costs of tuition and fees as indicated on the notice of grant award document will be paid directly to the school upon receipt of an invoice from the school. The portion of the scholarship grant awarded for the costs of equipment, supplies, books, and living expenses will be paid to the individual in equal monthly installments.

§ 57.2209 Conditions of scholarship grant.

(a) Any scholarship grant made to any individual under this subpart shall be awarded upon the condition that such individual will, following completion of his professional training, engage in the full-time practice of primary care for a period of 12 continuous months for each academic year (i.e., 9 months) for which a scholarship grant was made, as follows:

(1) In the case of any individual selected pursuant to § 57.2205(a) (1) or (2), such practice must be in the physician shortage area to which such individual agreed to return: *Provided however,* That if the Secretary determines at the time the individual proposes to engage in the required practice that such area is no longer a physician shortage area and cannot reasonably be expected to become such an area within 2 years from such time, such practice shall, at the option of the individual, be either in any then current physician shortage area, or in such place or places, facility, or facilities, and in such manner as the Secretary finds necessary to assure that, of the patients receiving medical care in such practice, a substantial portion will consist of persons who are migratory agricultural workers or members of their families.

(2) In the case of any individual selected pursuant to § 57.2205(a) (3) or (4), such practice must be in accordance with the agreement described in § 57.2205(b)(2) (i.e., in a physician shortage area with a substantial portion of migratory agricultural workers in such area; a physician shortage area; or in such place or places, facility or facilities, and in such manner as may be necessary to assure that, of the patients receiving medical care in such practice, a substantial portion will consist of persons who are migratory agricultural workers or members of their families; as the case may be).

(b) Subject to the provision of § 57.2211(f) and except as provided in paragraph (c) of this section, any individual to whom the conditions of this section apply must complete the practice required by paragraph (a) of this section within a period beginning on the date of completion by the individual of his professional training, as determined by the Secretary, and not to exceed the period of practice determined in accordance with such paragraph (a) of this section, plus 6 months.

(c) Where an individual to whom the conditions of this section apply is currently performing an active duty service obligation under section 235 of the Act, the individual must complete the practice required by paragraph (a) of this section within a period beginning on the date of completion by the individual of his service obligation under section 225 of the Act or completion of his internship and residency training (not to exceed four years) if not previously received, whichever comes later, and not to exceed the period of practice determined in accordance with paragraph (a) of this section, plus 6 months.

(d) Where an individual has received scholarship grant support for four academic years, such individual shall be considered to have received scholarship grant support for only three academic years if the Secretary determines (1) that such individual has served his internship or residency in a hospital (i) which is located in a physician shortage area, or (ii) in which a substantial portion of the patients of such hospital consists of persons who are migratory agricultural workers or members of the families of such workers and (2) that while so serving such internship or residency, he has received training or professional experience designed to prepare him to engage in the practice of primary care.

(e) For purposes of paragraph (c)(2) of this section, (1) internships which will be recognized by the Secretary as providing training or professional experience designed to prepare an individual to engage in the practice of primary care are: Rotating internships without a major emphasis, rotating internships with an emphasis on internal medicine, rotating internships with an emphasis on pediatrics, rotating internships with an emphasis on obstetrics and gynecology, straight internships in internal medicine, straight internships in pediatrics and straight internships in obstetrics and gynecology; *Provided,* That such internships are approved or provisionally approved by the Council on Medical Education of the American Medical Association or the Board of Trustees of the American Osteopathic Association; and

(2) Residencies which will be recognized as providing such training or experience are those in general practice,

family practice, general internal medicine, general pediatrics and general obstetrics and gynecology; *Provided*, That such residencies are approved or provisionally approved by the Council on Medical Education of the American Medical Association or the Board of Trustees of the American Osteopathic Association.

(f) No individual who has received a scholarship grant under this subpart may enter into an agreement with the Secretary pursuant to section 741(f) of the Act until either (1) such individual has completed the practice required by paragraph (a) of this section, or (2) the Secretary has determined that the United States is entitled to recover from such individual an amount determined in accordance with § 57.2210. In no case, however, shall a scholarship grant under this subpart be considered an educational loan for purposes of section 741(f) of the Act.

[39 FR 28730, Aug. 9, 1974, as amended at 41 FR 26685, June 29, 1976]

§ 57.2210 Failure to comply.

(a) Subject to the provision of § 57.2211, if any individual fails to complete the course of study or fails, within the time period set forth in § 57.2209(b), to meet the applicable conditions of practice imposed by receipt of a scholarship grant for the full number of months to which such condition is applicable, the United States shall be entitled to recover from such individual an amount determined in accordance with section 784(c)(3) of the Act; *Provided however*, That no interest shall accrue on any amount due the United States during any period for which the Secretary has suspended the obligation to repay pursuant to § 57.2211(b).

§ 57.2211 Waiver or suspension.

(a) Any obligation of any individual under this subpart will be cancelled upon the death of such individual as documented by a certification of death, or such other official proof as is conclusive under State law, and submitted to the Secretary.

(b) Subject to the provision of paragraph (f) of this section, where an individual fails to complete the practice required by § 57.2209(a) within the period prescribed in § 57.2209(b), the Secretary may waive or suspend for such period as determined by the Secretary the obligation of such individual to repay pursuant to § 57.2210 where the Secretary determines that compliance by such individual with such obligation (1) is impossible, or (2) would involve extreme hardship to such individual and enforcement of such obligation with respect to such individual would be against equity and good conscience.

(c) For purposes of paragraph (b)(1) of this section, compliance by an individual will be deemed impossible where the Secretary determines, on the basis of such information and documentation as he may require, that the individual is permanently and totally disabled.

(d) For purposes of paragraph (b)(2) of this section, in determining whether compliance by an individual would involve extreme hardship to such individual and would be against equity and good conscience, the Secretary will take into consideration the following:

(1) The individual's present financial resources and obligations;

(2) The individual's estimated future financial resources and obligations;

(3) The reasons for the individual's failure to complete such practice within the prescribed period, such as problems of a personal nature; and

(4) The extent to which the individual is practicing his profession in a manner consistent with the purposes of section 784 of the Act.

(e) Where the Secretary determines that compliance by an individual with his obligation to engage in the practice of primary care in a specified shortage area pursuant to § 57.2209(a) is impossible or would involve extreme hardship to such individual and enforcement of such obligation with respect to such individual would be against equity and good conscience, the Secretary may waive such obligation and permit the individual at his option to practice either in any then current physician shortage area, or in such place or places, facility or facilities, and in such manner as the Secretary finds necessary to assure that, of the patients receiving medical care in such practice, a substantial portion will consist of persons who are migratory agricultural workers or members of their families. The Secretary will take into consideration in determining whether to grant a waiver under this paragraph the extent to which the individual has problems of a personal nature, e.g., physical or mental disability, terminal illness in the family, or need for financial support that cannot be supplied by the required service, which intrude upon the individual's ability to perform the required service in the specified shortage area.

(f) The Secretary may extend the period (prescribed in § 57.2209(b)) within which an individual must complete the practice required pursuant to § 57.2209(a) for a period not to exceed one year where the Secretary finds that (1) such individual is unable to complete such practice within such period because of a temporary physical or mental disability, or (2) completion by such individual of such practice within such period would involve extreme hardship to such individual and that failure to so extend such period would be against equity and good conscience.

Subpart X—[Reserved]

Subpart Y—Grants for Nurse Practitioner Training Programs

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 822, 89 Stat. 361 (42 U.S.C. 296m).

SOURCE: 42 FR 60883, Nov. 29, 1977, unless otherwise noted.

§ 57.2401 Applicability.

The regulations of this subpart are applicable to the award of grants to public or nonprofit private schools of nursing, medicine, and public health, public or nonprofit private hospitals, and other public or nonprofit private entities under section 822 of the Public Health Service Act (42 U.S.C. 296m) to meet the cost of projects to (a) plan, develop, and operate, (b) significantly expand, or (c) maintain existing programs for the training of nurse practitioners.

§ 57.2402 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) "Council" means the National Advisory Council on Nurse Training (established by section 851 of the Act).

(d) "School of nursing" means a collegiate associate degree, or diploma school of nursing.

(e) "Collegiate school of nursing" means a department, division, or other administrative unit in a college or university which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to the degree bachelor of arts, bachelor of science, bachelor of nursing, or to an equivalent degree, or to a graduate degree in nursing, and including advanced training related to such program of education provided by such school, but only if such program, or such unit, college or university is accredited as provided in section 853(6) of the Act.

(f) "Associate degree school of nursing" means a department, division or other administrative unit in a junior college, community college, college, or university which provides primarily or exclusively a two-year program of education in professional nursing and allied subjects leading to an associate degree in nursing or to an equivalent degree, but only if such program, or such unit, college, or university is accredited as provided in section 853(6) of the Act.

(g) "Diploma school of nursing" means a school affiliated with a hospital or university, or an independent school, which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to a diploma or to equivalent indicia that such program has been satisfactorily completed, but only if such program, or such affiliated school or such hospital or university or such independent school is accredited as provided in section 853(6) of the Act.

(h) "School of medicine" means a school which provides training leading to a degree of doctor of medicine and which is accredited by a recognized body or bodies approved for such purpose by the Commissioner of Education.

(i) "School of public health" means a school which provides training leading to a graduate degree in public health and which is accredited by a recognized body or bodies approved for such purpose by the Commissioner of Education.

(j) "Nonprofit" as applied to any school, agency, organization, or institution means one which is a corporation or association, or is owned and operated by one or more corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(k) "State" means a State, the Commonwealth of Puerto Rico, the District of Columbia, the Canal Zone, Guam, American Samoa, the Virgin Islands, or the Trust Territory of the Pacific Islands.

(l) "Program director" means a qualified individual designated by the grantee and approved by the Secretary who is to be functionally responsible for the training program being supported under this subpart.

(m) "Project period" mean the total time for which support for a project has been approved, including any extensions thereof.

(n) "Budget period" means the interval of time into which the approved activity is divided for budgetary and reporting purposes.

(o) "Program for the training of nurse practitioners" or "nurse practitioner training program" means a full-time educational program for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) which meets the guidelines prescribed by the Secretary in the Appendix to this subpart and which has as its objective the education or nurses (including pediatric and geriatric nurses) who will, upon completion of their studies in such program, be qualified to effectively perform in an expanded role in the delivery of primary health care, including primary health care in homes and in ambulatory care facilities, long-term care facilities, and other health care institutions.

(p) "Nurse practitioner" means a registered nurse who has successfully completed a formal program of study designed to prepare registered nurses to perform in an expanded role in the delivery of primary health care including the ability to:

(1) Assess the health status of individuals and families through health and medical history taking, physical examination, and defining of health and developmental problems;

(2) Institute and provide continuity of health care to clients (patients), work with the client to insure understanding of and compliance with the therapeutic regimen within established protocols, and recognize when to refer the client to a physician or other health care provider;

(3) Provide instruction and counseling to individuals, families, and groups in the areas of health promotion and maintenance, including involving such persons in planning for their health care; and

(4) Work in collaboration with other health care providers and agencies to provide, and where appropriate, coordinate services to individuals and families.

(q) "Primary health care" means care which may be initiated by the client or provider in a variety of settings and which consists of a broad range of personal health care services including:

(1) Promotion and maintenance of health;

(2) Prevention of illness and disability;

(3) Basic care during acute and chronic phases of illness;

(4) Guidance and counseling of individuals and families; and

(5) Referral to other health care providers and community resources when appropriate.

In providing such services (i) the physical, emotional, social, and economic status, as well as the cultural and environmental backgrounds, of individuals, families, and communities (where applicable) are considered; (ii) the client is provided access to the health care system; and (iii) a single provider or team of providers, along with the client, is responsible for the continuing coordination and management of all aspects of basic health services needed for individual and family care.

§ 57.2403 Eligibility.

(a) *Eligible applicants.* To be eligible for a grant under this subpart the applicant shall:

(1) Be a public or nonprofit private school of nursing, medicine, or public health, public or nonprofit private hospital; or other public or nonprofit private entity; and

(2) Be located in a State.

(b) *Eligible projects.* A grant under this subpart may be made to an eligible applicant to meet the cost of:

(1) A project to plan, develop, and operate a program for the training of nurse practitioners (which will be in operation no later than 12 months after the award of a grant under this subpart);

(2) A project to significantly expand a program for the training of nurse practitioners through one or a combination of the following activities:

(i) A planned increase in student enrollment,

(ii) The addition to the program of one or more fields of clinical practice, or

(iii) The addition of a new training site for the total program; or

(3) A project to maintain an existing program for the training of nurse practitioners.

§ 57.2404 Application.

(a) Each eligible applicant desiring a grant under this subpart shall submit an application in such form and at such time as the Secretary may prescribe.[1]

(b) The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations of this subpart.

(c) In addition to such other pertinent information as the Secretary may require, an application for a grant under this subpart shall contain the following:

(1) A full and adequate description of the proposed project, including:

(i) Information concerning the need for and significance of the proposed project.

(ii) A description of the setting in which the training program will be conducted and the primary health care needs to which such program will be responsive.

(iii) A detailed description of the planning and developmental activities to be carried out or which have been accomplished by the applicant.

(iv) A detailed time plan for each year of the project period, identifying target dates for project activities and including any plans for continuing such activities beyond the project period.

(v) A description of specific measurable objectives for the proposed project consistent with the purposes of section 822 of the Act.

(vi) A detailed plan for achieving the stated objectives of the proposed project.

(vii) A description of the program curriculum, including course content and the number of hours of classroom instruction, supervised laboratory, and clinical practice.

(viii) A plan and methodology for evaluating the training program in accordance with the requirements of § 57.2405(c).

(ix) Where the training includes a preceptorship, a description of such preceptorship, including length, type of practice, and amount of faculty supervision.

(x) A description of recruitment plans and criteria for the selection and admission of students.

(xi) An estimate of the number of students to be enrolled during the project period.

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[1] Applications and instructions may be obtained from the Division of Nursing, Bureau of Health, Manpower, Health Resources Administration, Department of Health and Human Services, Center Building, Room 3-50, 3700 East-West Highway, Hyattsville, Md. 20782.

(xii) In the case of a project to significantly expand a nurse practitioner training program, a description of the manner in which the program is to be expanded and a plan for achieving such expansion during the project period.

(2) Evidence satisfactory to the Secretary that the applicant has secured any required institutional clearances and approvals for the planning, development, and operation of the program.

(3) Information concerning the background and qualifications of the program director, staff, and consultants.

(4) Evidence satisfactory to the Secretary that the applicant will have available adequate faculty, staff facilities, clinical practice settings, and equipment for the conduct of the proposed project.

(5) A description of any written agreements with other institutions or organizations for carrying out the proposed project.

(6) A detailed budget for the proposed project and a justification of the amount of grant funds requested.

(7) A description of financial resources available to the applicant to assure the sound establishment, maintenance, and continuation of the proposed project beyond the project period.

(8) Where the proposed project includes the cost of providing nurse faculty members with the clinical preparation necessary to meet the guidelines set forth in the Appendix to this subpart, a description of the faculty to be trained, the type of training required, and the manner in which such training will be obtained.

(9) Evidence that all applicable requirements of section 1513(e) of the Act have been met.

(d) The application shall contain an assurance satisfactory to the Secretary that (1) in the case of a project to plan, develop, and operate a program for the training of nurse practitioners, such program will upon its development meet the guidelines set forth in the Appendix to this subpart, or (2) in the case of a project to significantly expand or maintain an existing program for the training of nurse practitioners, such program meets the guidelines set forth in the appendix to this subpart.

§ 57.2405 Project requirements.

A project supported under this subpart shall be conducted in accordance with the following requirements:

(a) The project shall conduct its program for the training of nurse practitioners in accordance with the guidelines prescribed by the Secretary and set forth in the Appendix to this subpart.

(b) The program director shall be responsible for the conduct of the training program unless replaced by another individual found by the Secretary to be qualified to carry out such responsibilities. Where the program director becomes unable to function in such capacity, the Secretary shall be notified as soon as possible.

(c) In accordance with the plan set forth in its approved application, the project shall collect, evaluate, and make available to the Secretary data concerning the training program being conducted. Such data collection and evaluation shall include, at a mininum:

(1) Systematic evaluation by faculty and students of the program curriculum in relation to the purposes, objectives, and conceptual framework of the program.

(2) Evaluation of the effectiveness of the program in relation to its purposes and objectives.

(3) Information concerning the number of student applicants and students enrolled, student characteristics (such as age, sex, race, educational background, and previous work experience, including type of position, specialty, and work setting), and student performance in classroom work and clinical practice.

(4) Information concerning the number of graduates per class, the attrition rate, characteristics of graduates (such as age, sex, race, educational background, and previous work experience, including type of position, specialty, and work setting), employment after graduation (including setting and location), and utilization and performance of graduates (including employer assessment).

§ 57.2406 Evaluation and grant awards.

(a) *Evaluation.* (1) Within the limits of funds available for such purpose, the Secretary, after consultation with the Council, may award grants to those applicants whose projects will in his judgment best promote the purposes of section 822 of the Act, taking into consideration:

(i) The degree to which the project plan adequately provides for meeting the requirements set forth in § 57.2405 and the Appendix to this subpart;

(ii) The potential effectiveness of the proposed project in carrying out the training purposes of section 822 of the Act and this subpart;

(iii) The capability of the applicant to carry out the proposed project;

(iv) The extent to which the project has joint program direction by qualified nurse and physician educators;

(v) The soundness of the fiscal plan for assuring effective utilization of grant funds; and

(vi) The potential of the project to continue on a self-sustaining basis after the project period.

(2) Pursuant to section 822(a)(1) of the Act, the Secretary will give special consideration to:

(i) Projects for programs for the training of nurse practitioners who will practice in health manpower shortage areas (designated under section 332 of the Act); and

(ii) Projects for training programs which emphasize training respecting the special problems of geriatric patients and training to meet the particular needs of nursing home patients.

(3) The Secretary will also give special consideration to projects for nurse practitioner programs which will award academic credit to students who successsfully complete the training program.

(b) *Grant awards.* (1) The amount of any award under this subpart will be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of the direct costs of the project plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either (i) on the basis of his estimate of the actual indirect costs reasonably related to the project, or (ii) on the basis of a percentage of all or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(2) All grant awards shall be in writing and shall set forth the amount of funds granted and the period for which such funds will be available for obligation by the grantee.

(3) Neither the approval of any project nor the award of any grant shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application at such times and in such form as the Secretary may prescribe.

(c) *Noncompeting continuation awards.* If a grantee has filed an application for continuation support and within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period for any previously approved project if (1) the application is for a project which meets the regulations of this subpart and (2) on the basis of such progress and accounting records as may be required, the Secretary finds that the project's activities during the current budget period justify continued support of the project for an additional budget period. If the Secretary decides to continue support, the amount of the grant award will be determined in accordance with paragraph (b)(1) of this section. If the Secretary decides not to continue supporting a project for an additional budget period, he will notify the grantee in writing before the end of the current budget period. In addition, the Secretary may provide financial support for the orderly phaseout of the supported project, if he determines that such support is necessary.

§ 57.2407 Grant payments.

The Secretary will from time to time make payments to the grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the budget period, or in advance for expenses to be incurred, to the extent he determines such payments necessary to promote prompt intitiation and advancement of the approved project.

§ 57.2408 Expenditure of grant funds.

(a) Any funds granted pursuant to this subpart shall be expended solely for carrying out the approved project in accordance with section 822 of the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74; *Provided*, That such funds shall not be expended for sectarian instruction or for any religious purpose.

(b) Funds granted pursuant to this subpart may be used in accordance with an approved application for the clinincal training of nurse faculty members in order to meet the guidelines set forth in Appendix A.

(c) Any unobligated grant funds remaining in the grant account at the close of a budget period may be carried forward and be available for obligation during subsequent budget periods of the project period. The amount of a subsequent award will take into consideration the amount remaining in the grant account. At the end of the last budget period of the project period, any unobligated grant funds remaining in the grant account must be refunded to the Federal Government.

§ 57.2409 Nondiscrimination.

(a) Attention is called to the requirements of section 855 of the Act and 45 CFR Part 83 which together provide that the Secretary may not make a grant, loan guarantee, or interest subsidy payment under Title VIII of the Act to, or for the benefit of, any entity unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary that the entity will not discriminate on the basis of sex in the admission of individuals to its training programs.

(b) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.), and in particular to section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such Title VI, which is applicable to grants made under this subpart, has been issued by the Secretary with the approval of the President (45 CFR Part 80).

(c) Attention is called to the requirements of Title IX of the Education Amendments of 1972 and in particular to section 901 of such Act which provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance. A regulation implementing such Title IX, which is applicable to grants made under this subpart, has been issued by the Secretary with the approval of the President (45 CFR Part 86).

(d) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such section 504, which is applicable to grants made under this subpart, has been issued by the Secretary (45 CFR Part 84).

(e) Grant funds used for alteration or renovation shall be subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, 30 FR 12319 (Sept. 24, 1965) as amended, and with the applicable rules, regulations, and procedures prescribed pursuant thereto.

(f) The grantee shall not discriminate on the basis of religion in the admission of individuals to its training programs.

§ 57.2410 Human subjects.

No award may be made under this subpart unless the applicant has complied with 45 CFR Part 46 and any other applicable requirements pertaining to the protection of human subjects.

§ 57.2411 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from the other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart; *Provided,* That when the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total or selected elements of the reimbursable direct costs incurred.

(b) *Accounting for copyright royalties.* Royalties received by grantees from copyrights on publications or other works developed under the grant shall be accounted for as follows:

(1) Royalties received during the period of grant support may be retained by the grantee and, in accordance with the terms and conditions of the grant, used in either or both of the following ways:

(i) Used by the grantee for any purposes that further the objectives of section 822 of the Act.

(ii) Deducted from the total project costs for the purpose of determining the net costs on which the Federal share of costs will be based.

(2) Royalties received after the completion or termination of grant support may be retained by the grantee, unless the terms and conditions of the grant or a specific agreement negotiated between the Secretary and the grantee provide otherwise, except that any grantee that is a State or local government as defined in 45 CFR 74.3 which receives royalties in excess of $200 a year must return the Federal share of the excess amount (computed by applying the percentage of Federal participation in the cost of the grant supported project to the excess amount) to the Federal Government, unless a specific agreement provides otherwise.

(c) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of (i) any amount not accounted for pursuant to paragraphs (a) and (b) of this section; and (ii) any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74. Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assigns by setoff or other action as provided by law.

§ 57.2412 Publications and copyright.

(a) *State and local governments.* Where the grantee is a State or local government as those terms are defined in 45 CFR 74.3, the Department of Health and Human Services copyright requirement set forth in 45 CFR 74.140 shall apply with respect to any book or other copyrightable materials developed or resulting from a project supported by a grant under this subpart.

(b) *Grantees other than State and local governments.* Where the grantee is not a State or local government, as so defined, except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from a project supported by a grant under this subpart, subject to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials, and to authorize others to do so.

§ 57.2413 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in Subpart A of Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to all other grantee organizations under this subpart:

Subpart:	
A	General.
B	Cash depositories.
C	Bonding and insurance.
D	Retention and custodial requirements for records.
F	Grant-related income.
K	Grant payment requirements.
L	Budget revision procedures.
M	Grant closeout, suspension, and termination.
O	Property.
Q	Cost principles.

§ 57.2414 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

APPENDIX

GUIDELINES FOR NURSE PRACTITIONER TRAINING PROGRAMS

The guidelines set forth below have been prescribed by the Secretary after consultation with appropriate educational organizations and professional nursing and medical organizations, as required by section 822(a)(2)(B) of the Public Health Service Act.

A. *Definitions.* 1. "Programs for the training of nurse practitioners" or "nurse practitioner training program" means a full-time educational program for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) which meets the guidelines prescribed herein and which has as its objective the education of nurses (including pediatric and geriatric nursees) who will, upon completion of their studies in such program, be qualified to effectively perform in an expanded role in the delivery of primary health care, including primary health care in homes and in ambulatory care facilities, long-term care facilities, and other health care institutions.

2. "Nurse practitioner" means a registered nurse who has successfully completed a formal program of study designed to prepare registered nurses to perform in an expanded role in the delivery of primary health care including the ability to:

a. Assess the health status of individuals and families through health and medical history taking, physical examination, and defining of health and developmental problems;

b. Institute and provide continuity of health care to clients (patients), work with the client to insure understanding of and compliance with the therapeutic regimen within established protocols, and recognize when to refer the client to a physician or other health care provider;

c. Provide instruction and counseling to individuals, families and groups in the areas of health promotion and maintenance, including involving such persons in planning for their health care; and

d. Work in collaboration with other health care providers and agencies to provide, and where appropriate, coordinate services to individuals and families.

3. "Primary health care" means care which may be initiated by the client or provider in a variety of settings and which consists of a broad range of personal health care services including:

a. Promotion and maintenance of health;

b. Prevention of illness and disability;

c. Basic care during acute and chronic phases of illness;

d. Guidance and counseling of individuals and families; and

e. Referral to other health care providers and community resources when appropriate.

In providing such services (i) the physical, emotional, social, and economic status, as well as the cultural and environmental backgrounds of individuals, families, and communities (where applicable) are considered; (ii) the client is provided access to the health care system; and (iii) a single provider or team of providers, along with the client, is responsible for the continuing coordination and management of all aspects of basic health services needed for individual and family care.

B. *Organization and administration.* 1. A nurse practitioner training program shall have active collaboration with nurses and physicians who have expertise relevant to

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the nurse practitioner role and primary health care, to assist in the planning, development, and operation of such a program. In addition, where the institution or organization conducting the program is other than a school of nursing, medicine, or public health, such collaboration shall be with nurses and physicians who are affiliated with either a collegiate school of nursing, school of medicine, or school of public health.

2. Co-program directors from nursing and medicine are recommended.

C. *Student enrollment.* 1. A nurse practitioner training program shall have an enrollment of not less than eight full-time students in each class.

2. All students enrolled in a nurse practitioner training program must be licensed to practice nursing (a) at the time of enrollment, or (b) in the case of a program leading to a graduate degree in nursing, at or prior to the time of completion of the program.

3. The policies for the recruitment and selection of students shall be consistent with the requirements of the sponsoring institution and developed in cooperation with the faculty responsible for conducting the training. Admission criteria shall take into consideration the educational background and work experience of applicants.

D. *Length of program.* A nurse practitioner training program shall be a minimum of one academic year (or nine months) in length and shall include at least four months (in the aggregate) of classroom instruction.

E. *Curriculum.* 1. A nurse practitioner training program shall be a discrete program consisting of classroom instruction and faculty-supervised clinical practice designed to teach registered nurses the knowledge and skills needed to perform the functions of a nurse practitioner specified in the definition of that term as set forth in these guidelines. The curriculum shall be developed and implemented cooperatively by nurse educators, physicians, and appropriate representatives of other health disciplines. The following are examples of broad areas of program content which should be included: Communications and interviewing (history taking); basic physical examination including basic pathophysiology; positive health maintenance; care during acute and chronic phases of illness; management of chronic illness; health teaching and counseling; role realignment and establishment of collaborative roles with physicians and other health care providers; and community resources. The program content, both classroom instruction and clinical practice, should be developed so that the nurse practitioner is prepared to provide primary health care as defined in these guidelines.

2. The curriculum may include a preceptorship, in which the student is assigned to a designated preceptor (a nurse practitioner or physician) who is responsible for teaching, supervising, and evaluating the student and for providing the student with an environment which permits observation and active participation in the delivery of primary health care. If a preceptorship is included, it shall be under the direction and supervision of the faculty.

F. *Faculty qualifications.* A nurse practitioner training program shall have a sufficient number of qualified nursing and medical (and other related professional) faculty with academic preparation and clinical expertise relevant to their areas of teaching responsibility and with demonstrated ability in the development and implementation of educational programs.

G. *Resources.* 1. A nurse practitioner training program shall have available sufficient educational and clinical resources including a variety of practice settings, particularly in ambulatory care.

2. Clinical practice facilities shall be adequate in terms of space and equipment, number of clients, diversity of client age, and need for care, number of students enrolled in the program, and other students using the facility for training purposes.

3. Where the institution or organization conducting the program does not provide the clinical practice settings itself, it shall provide for such settings through written agreements with other appropriate institutions or organizations.

4. Where the institution or organization conducting the program is other than a school of nursing, medicine, or public health, it shall provide for sufficient educational expertise through writttten agreeements with a collegiate school of nursing, school of medicine, or school of public health.

[42 FR 60883, Nov. 29, 1977, as amended at 43 FR 27837, June 27, 1978]

Subpart Z—Grants for Advanced Nurse Training Programs

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 821, 89 Stat. 361 (42 U.S.C. 296*l*).

SOURCE: 43 FR 43416, Sept. 25, 1978, unless otherwise noted.

§ 57.2501 Applicability.

The regulations of this subpart apply to the award of grants to public and nonprofit private collegiate schools of nursing under section 821 of the Public Health Service Act (42

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U.S.C. 296*l*) to meet the costs of projects to: (a) Plan, develop, and operate, (b) significantly expand, or (c) maintain existing programs for the advanced training of professional nurses to teach in the various fields of nurse training, to serve in administrative or supervisory capacities, or to serve in other professional nursing specialties (including service as nurse clinicians) determined by the Secretary to require advanced training.

§ 57.2502 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"Council" means the National Advisory Council on Nurse Training established by section 851(a) of the Act.

"Budget period" means the interval of time into which the approved activity is divided for budgetary purposes, as specified in the grant award document.

"Project period" means the total time for which support for a project has been approved, as specified in the grant award document.

"State" means a State, the Commonwealth of Puerto Rico, the District of Columbia, the Canal Zone, Guam, American Samoa, the Virgin Islands, or the Trust Territory of the Pacific Islands.

"Collegiate school of nursing" means a department, division, or other administrative unit in a college or university which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to the degree of bachelor of arts, bachelor of science, bachelor of nursing, or to an equivalent degree, or to a graduate degree in nursing, and including advanced training related to this type of educational program provided by the school, but only if the program, or unit, college or university is accredited.

"Advanced nurse training program" means a program of study in a collegiate school of nursing leading to a graduate degree in nursing which trains professional nurses to teach in the various fields of nurse training, to serve in administrative or supervisory capacities, or to serve in other professional nursing specialties (including service as nurse clinicians) determined by the Secretary to require advanced training. For purposes of this section, the Secretary has determined that the following professional nursing specialties require advanced nurse training: (1) Geriatric nursing, (2) community health nursing, (3) maternal-child nursing, (4) acute care nursing, (5) medical-surgical nursing, and (6) adult nursing.

"Professional nurse" means a registered nurse who has received initial nursing preparation from a diploma, associate degree, or collegiate school of nursing as defined in section 853 of the Act and who is currently licensed to practice nursing.

"Nonprofit" as applied to any school means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures or may lawfully inure, to the benefit of any private shareholder or individual.

"Construction" means (1) the construction of new buildings and the acquisition, expansion, remodeling, replacement, and alteration of existing buildings including architects' fees but not including the cost of acquisition of land (except in the case of acquisition of an existing building), offsite improvements, living quarters, or patient-care facilities, and (2) equipping new buildings and existing buildings, whether or not acquired, expanded, remodeled, or altered.

§ 57.2503 Eligibility.

(a) *Eligible applicants.* To be eligible for a grant under this subpart the applicant shall:

(1) Be a public or nonprofit private collegiate school of nursing.

(2) Be located in a State.

(b) *Eligible projects.*[1] A grant under this subpart may be made to an eligible applicant to meet the cost of:

(1) A project to plan, develop, and operate an advanced nurse training program (which will enroll students before the end of the project period);

(2) A project to significantly expand an advanced nurse training program through one of the following activities:

(i) The addition to the program of a new clinical or functional (administration or teaching) specialty area,

(ii) A planned increase in student enrollment during the project period, or

(iii) The addition of a new training site for the program; or

(3) A project to maintain an existing advanced nurse training program.

§ 57.2504 Application.

(a) Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at the time which the Secretary may require.[2]

(b) The application shall be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations of this subpart.

(c) In addition to other pertinent information which the Secretary may require, an application for a grant under this subpart shall contain:

(1) A proposal for a project to: (i) Plan, develop, and operate, (ii) significantly expand, or (iii) maintain an existing, advanced nurse training program.

(2) Information documenting the need for the proposed project.

(3) A description of specific attainable and measurable objectives for the proposed project consistent with the purposes of section 821 of the Act.

(4) A detailed plan for achieving and measuring the stated objectives of the proposed project.

(5) A description of the anticipated impact of the proposed project, including its potential contribution to nursing.

(6) Evidence satisfactory to the Secretary that the applicant will have available adequate resources for the conduct of the proposed project, including adequate faculty, staff, equipment, facilities, and an appropriate clinical practice setting or settings.

(7) A detailed budget for the proposed project and a justification of the amount of grant funds requested.

(8) A description of any Federal financial support related to the proposed project which the applicant is currently receiving.

(9) A detailed timetable for carrying out the activities of the proposed project, including any plans for continuing activities beyond the project period.

(10) A description of the background and qualifications of the project staff and any proposed consultants.

(11) Information concerning the source and number of potential students for the training program, and a description of plans, if any to encourage graduates of the training program to practice in States in need of nurses trained in the specialty in which training is to be provided.

(d) In the case of a project to significantly expand or to maintain an existing advanced nurse training program, the application shall contain an assurance satisfactory to the Secretary that the applicant will expend, in carrying out the program during the fiscal year for which a grant under this subpart is sought, an amount of non-Federal funds (excluding costs of construction) at least as great as the average amount of non-Federal funds (excluding expenditures of a nonrecurring nature, including costs of construction) expended for this purpose during the 3 fiscal years immediately preceding the fiscal year for which the grant is sought.

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[1] Projects for training not in one of the specialty areas identified in the definition of "advanced nurse training" under § 57.2502, which received a grant prior to the effective date of these final regulations, may receive continuation support through the end of the approved period of support, subject to the satisfactory progress of the project and the availability of funds. However, any additional continuation or expansion of a project awarded a grant prior to this effective date will be approved only if the project is for training in one of the identified specialty areas and meets all other requirements of this subpart.

[2] Applications and instructions may be obtained from the Division of Nursing, Bureau of Health Manpower, Health Resources Administration, Department of Health and Human Services, Center Building, Room 3-50, 3700 East-West Highway, Hyattsville, Md. 20782.

§ 57.2505 Project requirements.

(a) A project supported under this subpart shall be conducted in accordance with its approved application.

(b) A project supported under this subpart shall enroll professional nurses, as defined in § 57.2502, or students who will be professional nurses, as defined in § 57.2502, at or prior to completion of the advanced nurse training program.

§ 57.2506 Evaluation and grant awards.

(a) *Evaluation.* Within the limits of funds available for this purpose, the Secretary, after consultation with the Council, may award grants to those applicants whose projects will, in his or her judgment, best promote the purposes of section 821 of the Act, taking into consideration among other pertinent factors:

(1) The need for the proposed project including, with respect to projects to provide training in professional nursing specialties determined by the Secretary to require advanced training: (i) The current or anticipated need for professional nurses trained in the specialty; and (ii) the relative number of programs offering advanced training in the specialty;

(2) The need for nurses in the specialty in which training is to be provided in the State in which the training program is located, as compared with the need for these nurses in other States;

(3) The degree to which the applicant proposes to recruit students from States in need of nurses in the specialty in which training is to be provided, and to promote their return to these States following training;

(4) The degree to which the applicant proposes to encourage graduates to practice in States in need of nurses in the specialty in which training is to be provided;

(5) The potential effectiveness of the proposed project in carrying out the training purposes of section 821 of the Act and this subpart;

(6) The capability of the applicant to carry out the proposed project;

(7) The soundness of the fiscal plan for assuring effective utilization of grant funds; and

(8) The potential of the project to continue on a self-sustaining basis after the period of grant support.

(b) *Funding preference.* In making awards under this paragraph, the Secretary will give preference to applications for projects for advanced nurse training in geriatric nursing, community health nursing, and maternal-child nursing.

(c) *Grant awards.* (1) The amount of any award under this subpart will be determined by the Secretary on the basis of his or her estimate of the sum necessary for all or a designated portion of the direct costs of the project plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (i) On the basis of his or her estimate of the actual indirect costs reasonably related to the project, or (ii) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of this percentage will not exceed the approximate actual indirect costs. The award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(2) All grant awards shall be in writing and shall set forth the amount of funds granted and the period for which the funds will be available for obligation by the grantee.

(3) Neither the approval of any project nor the award of any grant shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually in a

form and at the time that the Secretary may require.

(d) *Noncompeting continuation awards.* Within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period for any previously approved project on the basis of an application and those progress and accounting records which may be required. If the Secretary finds that the project's activities during the current budget period justify continued support of the project for an additional budget period, and the Secretary decides to continue support, the amount of the grant award will be determined in accordance with paragraph (c)(1) of this section. If the Secretary decides not to continue support for an additional budget period, he or she will notify the grantee in writing before the end of the current budget period. The Secretary may provide financial support for the orderly phase-out of the supported project, if he or she determines that this support is necessary.

§ 57.2507 Grant payments.

The Secretary will from time to time make payments to the grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the budget period, or in advance for expenses to be incurred, to the extent he or she determines these payments necessary to promote prompt initiation and advancement of the approved project.

§ 57.2508 Expenditure of grant funds.

(a) Any funds granted under this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with section 821 of the Act, the regulations of this subpart, the terms and conditions of the award, except that funds shall not be expended for sectarian instruction or for any religious purpose.

(b) Any unobligated grant funds remaining in the grant account at the close of a budget period may be carried forward and be available for obligation during subsequent budget periods of the project period. The amount of a subsequent award will take into consideration the amount remaining in the grant account. At the end of the last budget period of the project period, any unobligated grant funds remaining in the grant account must be refunded to the Federal Government.

57.2509 Nondiscrimination.

(a) Recipients of grants under this subpart are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations are applicable:

(1) Section 855 of the Act (42 U.S.C. 298b-2) and its implementing regulation, 45 CFR Part 83 (prohibiting discrimination on the basis of sex in the admission of individuals to training programs).

(2) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq. and its implementing regulation, 45 CFR Part 80 (prohibiting discrimination in federally assisted programs on the ground of race, color, or national origin).

(3) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) and its implementing regulation, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in federally assisted education programs).

(4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and its implementing regulation, 45 CFR Part 84 (prohibiting discrimination in federally assisted programs on the basis of handicap).

(b) The grantee shall not discriminate on the basis of religion in the admission of individuals to its training programs.

§ 57.2510 Human subjects.

No award may be made under this subpart unless the applicant has complied with 45 CFR Part 46 and any other applicable requirements pertaining to the protection of human subjects.

§ 57.2511 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart. When the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of these predetermined fixed-percentage rates applied to the total or selected elements of the reimbursable direct costs incurred.

(b) *Accounting for royalties.* Royalties received by grantees from copyrights on publication or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under the grant shall be accounted for as follows:

(1) Royalties received during the period of grant support as a result of copyrights or patents may be retained by the grantee and, in accordance with the terms and conditions of the grant, use in either or both of the following ways:

(i) Used by the grantee for any purposes that further the objectives of section 821 of the Act.

(ii) Deducted from the total project costs for the purpose of determining the net costs on which the Federal share of costs will be based.

(2) Royalties received after the completion or termination of grant support shall be treated as follows:

(i) Patent royalties will be governed by agreements between the Assistant Secretary for Health, Department of Health and Human Services, and the grantee under the Department's patent regulations (45 CFR Parts 6 and 8).

(ii) Copyright royalties may be retained by the grantee, unless the terms and conditions of the grant or a specific agreement negotiated between the Secretary and the grantee provide otherwise.

(c) *Grant closeout*—(1) *Date of final accounting.* A grantee shall submit, with respect to each approved project, a full account, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of: (i) Any amount not accounted for under paragraphs (a) and (b) of this section; and (ii) any other amounts due under Subparts F, M, and O of 45 CFR Part 74. This total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assigns by setoff or other lawful action.

§ 57.2512 Publications and copyright.

The policies of 45 CFR 74.140 shall apply to grants made under this subpart.

§ 57.2513 Applicability of 45 CFR Part 74.

The relevant provisions of the following subparts of Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants awarded under this subpart:

Subpart:

A General.
B Cash depositories.
C Bonding and insurance.
D Retention and custodial requirements for records.
F Grant-related income.
G Matching and cost sharing.
K Grant payment requirements.
L Budget revision procedures.
M Grant closeout, suspension, and termination.
O Property.
Q Cost principles.

§ 57.2514 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his or her judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

Subpart AA—Grants for Nurse Practitioner Traineeship Programs

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 822(b) of the Public Health Service Act, 91 Stat. 393 (42 U.S.C. 296m).

SOURCE: 45 FR 29804, May 6, 1980, unless otherwise noted.

§ 57.2601 To what programs do these regulations apply?

These regulations apply to grants awarded to schools of nursing, medicine, and public health, public or nonprofit private hospitals, and other nonprofit entities to meet the costs of traineeships under section 822(b) of the Public Health Service Act.

§ 57.2602 Definitions.

"Act" means the Public Health Service Act, as amended.

"Health manpower shortage area" means a geographic area, population group, public or nonprofit private medical facility, or other public facility which has been determined by the Secretary to have a shortage of health manpower under section 332 of the Act and its implementing regulations (42 CFR Part 5).

"National of the United States" means a citizen of the United States or a person who, though not a citizen of the United States, owes permanent allegiance to the United States (as defined in 8 U.S.C. 1101(a)(22), the Immigration and Nationality Act).

"Nonprofit," as applied to any entity, means an entity no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

"Nurse practitioner" means a registered nurse who has successfully completed a formal program of study designed to prepare registered nurses to perform in an expanded role in the delivery of primary health care, including the ability to:

(a) Assess the health status of individuals and families through health and medical history taking, physical examination, and defining health and developmental problems;

(b) Institute and provide continuity of health care to clients (patients), work with the client to insure understanding of and compliance with the therapeutic regimen within established protocols, and recognize when to refer the client to a physician or other health care provider;

(c) Provide instruction and counseling to individuals, families, and groups in the areas of health promotion and maintenance, including involving these persons in planning for their health care; and

(d) Work in collaboration with other health care providers and agencies to provide and, where appropriate, coordinate services to individuals and families.

"Nurse practitioner training program" means a full-time educational program for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) which meets the guidelines prescribed by the Secretary in 42 CFR Part 57, Subpart Y, Appendix. The objective of this program is the education of nurses (including pediatric and geriatric nurses) who will, upon completion of their studies in this program, be qualified to perform effectively in an expanded role in the delivery of primary health care, including care in homes, in ambulatory and long-term care facilities, and in other health care institutions.

"Primary health care" means care which may be initiated by the client or provider in a variety of settings and which consists of a broad range of personal health care services, including:

(a) Promotion and maintenance of health;

(b) Prevention of illness and disability;

(c) Basic care during acute and chronic phases of illness;

(d) Guidance and counseling of individuals and families; and

(e) Referral to other health care providers and community resources when appropriate.

"School of Medicine" or "school of public health" means a school of medicine or a school of public health as defined in section 701(4) of the Act, which is accredited under section 772(b) of the Act.

"School of nursing" means a collegiate, associate degree, or diploma school of nursing, as defined in section 853 of the Act.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services (HHS), to whom the authority involved has been delegated.

"State" means any one of the several states of the United States, the Commonwealth of Puerto Rico, the District of Columbia, Guam, American Samoa, the Virgin Islands, the Northern Mariana Islands or the Trust Territory of the Pacific Islands.

"Trainee" means a student who is receiving a traineeship from a grant under this subpart.

§ 57.2603 Who is eligible to apply for a grant?

Any school of nursing, medicine, or public health, public or nonprofit private hospital, or other public or nonprofit private entity which is located in a State and which provides nurse practitioner training programs is eligible to apply for a grant.

§ 57.2604 How to apply for a grant?

(a) The Secretary will periodically notify the public about the availability of grant applications and the deadlines for submitting them. An applicant must submit an application in the form and at the time that the Secretary requires.

(b) The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations of this subpart.

§ 57.2605 How will applications be evaluated?

(a) The Secretary will approve projects which will best promote the purposes of section 822(b) of the Act. The Secretary will take into consideration, among other factors:

(1) The adequacy of the qualifications and experience of the program director, staff and faculty to carry out the program; and

(2) The administrative and managerial ability of the applicant to carry out the proposed project.

(b) In determining priority for funding applicants approved under paragraph (a) of this section, the Secretary will give first preference to applicants who provide nurse practitioner training in schools of nursing that award academic credit to students who complete the program. The Secretary will give second preference to applicants other than schools of nursing that award academic credit to students who complete the program.

§ 57.2606 How long does grant support last?

(a) The notice of grant award specifies the length of time HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 3 years.

(b) Generally, the grant will initially be funded for one year, and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

(d) The Secretary may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the Secretary's written approval is obtained. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 57.2607 How is the amount of the award determined?

The amount of the award to the grantee will be determined on the basis of the Secretary's estimate of the sum necessary during the budget period to cover the trainees' costs of tuition, reasonable living and moving expenses (including stipends), books, fees, and necessary transportation.

§ 57.2608 For what purposes may grant funds be spent?

(a) Any funds granted under this subpart shall be spent solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

§ 57.2609 What financial support is available to trainees?

The grantee must pay each trainee, from grant funds, the entire cost of tuition and fees for the program, and a stipend and allowance, as set forth by the Secretary in the notice of grant award. This allowance must include costs incurred for:

(a) Books and equipment necessary to the course of study;

(b) Initial necessary travel from the trainee's residence to the training site;

(c) Travel required for clinical practice during the training program; and

(d) Necessary travel and moving expenses from the training site to the site of the obligated practice.

§ 57.2610 Who is eligible for financial assistance as a trainee?

To be eligible for a traineeship, an individual must:

(a) Be a national of the the United States or a permanent resident of the Trust Territory of the Pacific Islands or the Northern Mariana Islands, or a lawful permanent resident of the United States, Puerto Rico, the Virgin Islands, or Guam;

(b) Be accepted for enrollment, or be enrolled, as a full-time student in a nurse practitioner training program;

(c) Be a resident of a health manpower shortage area; and

(d) Have signed a commitment with the Secretary in accordance with § 57.2614.

§ 57.2611 What are the requirements for traineeships and the appointment of trainees?

(a) The grantee must require each trainee to complete a statement of appointment by the beginning of the training period. The program director must sign the statement of appointment and the grantee must retain it for three years.

(b) The grantee must require each trainee to agree to respond to communications from the Department of Health and Human Services regarding the trainee's professional activities for five years following completion of the training program for which the traineeship is awarded.

(c) The grantee must require each trainee to sign a commitment with the Secretary to practice as a nurse practitioner in a health manpower shortage area, designated as being short of primary medical care health manpower. The commitment must meet the requirements of § 57.2614.

(d) The grantee may not require trainees to perform any work which is not an integral part of the nurse practitioner training program and required of all students in the program.

(e) the grantee may not discriminate on the basis of religion in the admission of individuals to its training program.

§ 57.2612 Duration of traineeships.

Initial appointments to traineeships must be made for a full academic year, not to exceed 12 months, except that a shorter appointment may be made when necessary to enable the trainee to complete the training program. Appointments may be extended on a year-to-year basis. The total period of support for any trainee may not exceed 24 months.

§ 57.2613 Termination of traineeships.

The grantee must terminate a traineeship:

(a) Upon request of the trainee;

(b) If the trainee is no longer enrolled full-time in the nurse practitioner training program for which the trainee was receiving a traineeship under this subpart; or

(c) If the trainee fails to maintain the level of academic standing required by the institution's standards and practices for full-time enrollment.

§ 57.2614 What must a trainee do in return for traineeship support?

(a) *General.* Each trainee must sign a commitment with the Secretary to practice as a nurse practitioner on a full-time basis (at least 40 hours per week) in a health manpower shortage area designated as having a shortage of primary medical care manpower. At the end of the training program, the trainee must inform the Secretary of the location where he or she will be serving the practice commitment. The trainee must also inform the Secretary of any changes in name, address, and employment during this period of practice.

(b) *Duration of practice.* The period for which a trainee must agree to practice is equal to twelve months for each academic year for which the trainee receives support from grant funds. Once practice has begun, it must be continuous for the entire period of practice required by the commitment, unless the Secretary permits suspension of the obligation in accordance with § 57.2616.

(c) *Beginning of practice.* The trainee must begin the practice described in paragraph (a) of this section within three months of the completion of the training program.

§ 57.2615 What are the consequences if the trainee fails to comply with the terms of the commitment?

If a trainee fails to begin or complete the period of practice required by the commitment under § 57.2614, the trainee must repay the traineeship support to the United States Treasury. The amount of repayment must equal the sum of all traineeship support received, together with interest at the maximum legal prevailing rate in effect on the date the trainee initially received traineeship assistance, less an amount which bears the same ratio to this sum as the number of months the trainee has practiced in a health manpower shortage area, designated as having a shortage of primary medical care manpower, bears to the total number of months of practice required under the commitment. The trainee must pay the amount owed within 36 months of the date on which he or she failed to begin or complete the period of required practice, as determined by the Secretary.

§ 57.2616 When can the practice or payment obligation be cancelled or suspended?

(a) *Application for cancellation or suspension.* A trainee may seek cancellation or suspension of the commitment to practice or obligation to repay traineeship support by written request to the Secretary setting forth the basis, circumstances, and causes which support the requested action. The total period during which the practice or repayment obligation may be suspended may not exceed 2 years.

(b) *Conditions for suspension.* The Secretary may suspend any practice or repayment obligation whenever he or she finds good cause based on such factors as:

(1) The trainee's efforts to secure employment which satisfies the practice obligation;

(2) The trainee's present and estimated future financial resources and obligations; or

(3) The extent to which the trainee has problems of a personal nature, such as physical or mental disability, or terminal illness in the immediate family, which temporarily prevent the trainee from performing the obligation incurred.

(c) *Conditions for cancellation.* The Secretary may cancel any practice or repayment obligation:

(1) Upon the death of the trainee:

(2) If the trainee is found to be permanently and totally disabled as supported by whatever medical certification the Secretary may require. A trainee is totally and permanently disabled if he or she is unable to engage in any substantial gainful activity because of a medically determinable im-

pairment which is expected to continue indefinitely or result in death.

§ 57.2617 What additional Department regulations apply to grantees?

Several other regulations apply to grantees. They include, but are not limited to:

42 CFR Part 50—PHS grant appeals process

45 CFR Part 16—Department grant appeals process

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance from the Department—Implements Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs

45 CFR Part 84—Nondiscrimination on the basis of handicapped in Federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in Federally assisted education programs

45 CFR Part 91[1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance

§ 57.2618 What other record keeping, audit, and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act concerning record keeping, audit, and inspection.

§ 57.2619 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of any award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart BB—[Reserved]

Subpart CC—Scholarships for First-Year Students of Exceptional Financial Need

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 758, Public Health Service Act, 90 Stat. 2289 (42 U.S.C. 294z).

SOURCE: 45 FR 40583, June 16, 1980, unless otherwise noted.

§ 57.2801 To what programs do these regulations apply?

These regulations apply to grants under section 758 of the Public Health Service Act (42 U.S.C. 294z) for scholarships for full-time first-year students of exceptional financial need.

§ 57.2802 Definitions.

"Act" means the Public Health Service Act, as amended.

"First year of study" means the student's first year of post baccalaureate study at a health professions school leading to a degree specified in section 701(4) of the Act. For a health professions school with a course of study of more than 4 years, only the last 4 years will be considered as professional years and the first year of study will be the first of the last 4 years.

"Full-time student" means a student enrolled in a school and pursuing a course of study which constitutes a full-time academic workload, as determined by the school, leading to a degree from a health professions school, as specified in section 701(4) of the Act.

"Health professions school" or "school" means a public or private nonprofit school of medicine, osteopathy, dentistry, optometry, podiatry, pharmacy, or veterinary medicine providing a course of study, or a portion thereof, as defined in section 701(4) of the Act.

"National of the United States" means (1) a citizen of the United States, or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States, as defined in the Immigration and Nationality Act, at 8 U.S.C. 1101(a)(22).

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[1] When issued.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department to whom the authority involved has been delegated.

"State" means in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 57.2803 How to apply for a grant.

(a) Any health professions school located in a State may apply for a grant.

(b) In addition to other information that the Secretary may require, an application must contain:

(1) A listing of eligible scholarship recipients in order of greatest financial need, indicating resident or nonresident status as well.

(2) The name of the need analysis service used in evaluating the financial status of applicants.

§ 57.2804 Students eligible for scholarships.

(a) A scholarship may be awarded only to a student who:

(1) Is a national of the United States, or a permanent resident of the Trust Territory of the Pacific Islands or the Northern Mariana Islands or a lawful permanent resident of the United States, Puerto Rico, the Virgin Islands, or Guam.

(2) Has been accepted for enrollment as a full-time student in the first year of study by a health professions school.

(3) Has exceptional financial need as determined under paragraph (b) of this section.

(b)(1) For the purpose of this subpart, a student will have exceptional financial need if the school determines that his or her resources, as described in (b)(2) of this section, do not exceed the lesser of $5,000 or one-half of the cost of attendance at the school.

(2) The school will determine the financial resources of a student by using one of the national need analysis systems or any other procedure approved by the Secretary of Education and published under 45 CFR 144.13 and other information which the school has regarding the student's financial status. The school must take into account, regardless of the tax status of the student, the expected contribution from parents, spouse, or other family members. Student summer earnings, educational loans, veterans (G.I) benefits and earnings during the school year will not be considered resources for purposes of this subpart.

(3) The school will determine cost of attendance at the school by considering expenses reasonably necessary for the student's attendance at the school, including any special needs and obligations which directly affect the student's ability to attend the school on a full-time basis. The school must document the criteria used for determining these costs.

(c) A recipient of a National Health Service Corps Scholarship, under section 751 of the Act, or an Indian Health Scholarship, under section 757 of the Act, is ineligible for a scholarship under this subpart.

§ 57.2805 Amount of scholarship award.

A scholarship will consist of:

(a) The tuition of the student for the first year of study;

(b) The cost of all other reasonable educational expenses including fees, books, and laboratory expenses of the student for the school year; and

(c) A stipend of $400 per month (adjusted in accordance with section 751(g)(3) of the Act) for 12 consecutive months beginning with the first month of the school year.

§ 57.2806 How is the amount of grant award determined?

(a) A school which receives a grant under this subpart must award each scholarship successively to the eligible individual as specified in § 57.2803(b)(1) of greatest financial need at that school.

(b) The Secretary will make a randomized list of all eligible applicant schools of medicine, dentistry and osteopathy and a second randomized list of all remaining eligible applicant schools. To the extent of available funds, the Secretary will award grant funds sufficient for one scholarship to each eligible applicant school on the first list, and then proceed to the list of all other eligible applicant schools and award one scholarship to each school in the same manner. These scholarships must go to students who have no financial resources for the first year of study at the school, as determined under § 57.2804. The Secretary will then allocate any remaining funds according to paragraph (c) of this section.

(c)(1) Proceeding in sequence through the list of schools of medicine, dentistry and osteopathy, the Secretary will award each school of medicine, dentistry, and osteopathy sufficient grant funds for a second scholarship which must be given to a student with no financial resources for the first year of study at the school, as determined under § 57.2804. This procedure will be repeated until all the scholarship requests of the applicant schools of medicine, osteopathy, and dentistry for scholarships for students with no financial resources have been satisfied or until all the available grant funds have been allocated. If there are additional grant funds, the Secretary will then proceed to the list of all other eligible applicant schools and will allocate scholarships for students with no financial resources using the same procedure.

(2) If additional grant funds remain after fulfilling all requests for scholarships for students with no financial resources at all eligible applicant schools, using the method described in paragraph (c)(1) of this section the Secretary will allocate funds for scholarships to students who have resources from one to 500 dollars. With any remaining funds after completion of these awards, the Secretary will, in the same manner, award grants for scholarships to students with resources in increments of $500 until all grant funds are awarded or students who have $5,000 in resources or 50 percent of the cost of education at the school have received awards.

§ 57.2807 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application, the authorizing legislation, terms and conditions of the grant award, and these regulations.

(b) The grantee must discontinue all scholarship payments and remit the unused balance of the scholarship to the Federal Government in the event that a recipient ceases to be a full-time student at the school.

§ 57.2808 What additional Department regulations apply to grantees?

Several other regulations apply to these grants. They include, but are not limited to:

42 CFR Part 50—PHS grant appeals process

45 CFR Part 16—Department grant appeals process

45 CFR Part 74—Administration of grants

45 CFR Part 80—Nondiscrimination under programs receiving Federal Assistance from the Department—Implements Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs

45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in Federally assisted education programs

45 CFR Part 91[1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance

§ 57.2809 What other records, audit, and inspection requirements apply to grantees?

(a) Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act concerning recordkeeping, audit, and inspection.

(b) The grantee must also maintain: (1) A record of all applications for scholarships, and the basis for approving or disapproving each application, including a copy of the total need analysis and determination of resources for each applicant and documentation for any changes made to the need analysis report used by the school; (2) A record of the amount of funds awarded to each recipient.

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[1] When issued.

§ 57.2810 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of an award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart DD—Grants for Training United States Citizen Foreign Medical Students

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 782 of the Public Health Service Act, 90 Stat. 2314 (42 U.S.C. 295g-2).

SOURCE: 43 FR 36631, Aug. 18, 1978, unless otherwise noted.

§ 57.2901 Applicability.

The regulations of this subpart are applicable to the award of grants under section 782 of the Public Health Service Act (42 U.S.C. 295g-2) to schools of medicine and osteopathy to plan, develop, and operate training programs for U.S. citizens, who were students in foreign medical schools before October 12, 1976, (a) to enable them to meet the requirements for enrolling in schools of medicine or osteopathy in the States as full-time students with advanced standing, or (b) to train those U.S. citizen foreign medical students who have transferred from foreign medical schools and have enrolled in schools of medicine and osteopathy in the States as full-time students with advanced standing.

§ 57.2902 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Advanced standing" means the level of academic placement beyond the first year of training at a school of medicine or osteopathy in a State.

"Budget period" means the interval of time into which the project period is divided for budgetary and reporting purposes, as specified in the grant award.

"Council" means the National Advisory Council on Health Professions Education (established by section 702 of the Act).

"Foreign medical school" means a school (1) which is not located in a State, (2) which provides a full course of study leading to a medical degree or a diploma, and (3) whose medical degree or diploma is accepted by the country in which the school is located as one of the necessary qualifications for offical sanction or licensure to practice medicine as a physician in that country.

"Foreign medical student" means a U.S. citizen who was a student in a foreign medical school before October 12, 1976, and who is either: (1) seeking to transfer to a school of medicine or osteopathy in a State as a full-time student with advanced standing, or (2) has enrolled in a school of medicine or osteopathy in a State as a full-time student with advanced standing.

"Full-time student" means a student who is enrolled in a school in a State on a full-time basis, as determined by the school, and is pursuing a course of study leading to a degree of medicine or osteopathy.

"Nonprofit school" means a school owned and operated by one or more corporations or associations, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

"Project director" means an individual designated by the grantee in the grant application and approved by the Secretary to direct the project being supported under this subpart.

"Project period" means the total time for which support for a project has been approved, including any extensions thereof.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"School of medicine or school of osteopathy" means a school which provides training leading to a degree of doctor of medicine or a degree of doctor of osteopathy and is accredited as provided in section 772(b) of the Act.

"State" means one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 57.2903 Eligibility.

(a) *Eligible applicants.* Any public or private nonprofit school of medicine or osteopathy located in a State may apply for a grant under this subpart.

(b) *Eligible projects.* Grants under this subpart may be made to eligible applicants to meet the costs of planning, developing, and operating projects to carry out either one or both of the following purposes:

(1) To train U.S. citizens who were enrolled in foreign medical schools before October 12, 1976, to enable them to meet the requirements for enrolling in schools of medicine or osteopathy in the States as full-time students with advanced standing; or

(2) To train U.S. citizens who were enrolled in foreign medical schools before October 12, 1976, who have transferred from foreign medical schools and have enrolled in schools of medicine or osteopathy in the States as full-time students with advanced standing.

§ 57.2904 Application.

(a) Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at the time as the Secretary may require.[1] More than one school may join in the submission of an application for a grant under this subpart.

(b) The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award including the regulations of this subpart.

(c) In addition to other pertinent information as the Secretary may require, an application for a grant under this subpart must contain the following:

(1) A description of the proposed project to carry out either one or both of the purposes specified in § 52.2903(b).

(2) A description of any previous similar training activities in which the applicant has engaged.

(3) A description of the resources available for the conduct of the proposed project, including faculty, staff, equipment, facilities, and where applicable, the clinical practice setting or settings.

(4) A description of the background and qualifications of the project staff and any proposed consultants.

(5) A description of the proposed recruitment plans and criteria for admission to the training program.

(6) An estimate of the number of students to be enrolled in the training program.

(7) A description of the proposed plan and methods of identifying the deficiencies in the foreign medical school education of the foreign medical students participating in the training program as required by § 57.2905 of this subpart.

(8) A description of the proposed training program for correcting deficiencies including the proposed curriculum, the proposed number of hours for classroom instruction, and proposed laboratory demonstrations, lectures, and seminars.

(9) A description of the proposed plan to counsel foreign medical students who have completed a § 57.2903(b)(1) training program with respect to gaining admission as full-time students with advanced standing to schools of medicine or osteopathy located in the States.

(10) A detailed timetable for carrying out the activities of the proposed project.

(11) A detailed method for monitoring and evaluating the performance of the foreign medical student participants, and of the overall project.

(12) A detailed budget for the proposed project and a justification of the amount of grant funds requested.

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[1] Applications and instructions may be obtained from the Grants Management Officer, Bureau of Health Manpower, Room 4-22 Center Building, 3700 East-West Highway, Hyattsville, Md. 20782.

§ 57.2905 Project requirements.

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) The project must be conducted in accordance with section 782 of the act, the regulations of this subpart, the terms and conditions of the award, and the approved application.

(b) The project must be conducted under the direction of a project director who must be on the full-time faculty of a school submitting an application under this subpart. If the project director becomes unable to function in this capacity, the Secretary must be notified as soon as possible.

(c) Each training program must have at least four foreign medical student participants.

(d) Each project must systematically evaluate and monitor the progress of the foreign medical student participants during their training.

(e) If the project is designed to carry out the purpose of training foreign medical students to enable them to meet the requirements of enrolling in a school of osteopathy or medicine in a State (§ 57.2903(b)(1)), the project must:

(1) Identify the deficiencies in the foreign medical school education of each foreign medical student, including those subject areas which are lacking because the subjects are not part of the foreign medical school curricula, are not taught within a time-frame comparable to the curricula of U.S. schools of medicine or osteopathy or do not correspond sufficiently to subject areas taught in U.S. schools of medicine or osteopathy; and provide training to correct these deficiencies;

(2) Assess by examination or other appropriate mechanisms each foreign medical student's medical knowledge and skills in the basic, clinical, and behavioral sciences and provide, where necessary, supplemental training in these subject areas;

(3) Provide each foreign medical student with an evaluation of his or her overall performance, including examination scores, upon completion of the training program; and

(4) Counsel the foreign medical students who have completed the training program with respect to gaining admission as full-time students with advanced standing in schools of medicine or osteopathy located in the States.

(f) If the project is designed to carry out the purpose of training foreign medical students who have enrolled in a school of medicine or osteopathy in a State (§ 57.2903(b)(2)), the project must:

(1) Assess the medical knowledge and skills of the foreign medical students enrolled in the applicant school of medicine or osteopathy and compare the degree of their knowledge and skills with that possessed by students enrolled and trained in the applicant school of medicine or osteopathy at the same academic level as the foreign medical student; and

(2) Provide supplemental training to each foreign medical student whose medical knowledge and skills are not comparable to the degree of medical knowledge and skills possessed by students enrolled and trained in the applicant school of medicine or osteopathy at the same level as the foreign medical student in order to bring the foreign medical student to a degree of competency equal to these students.

§ 57.2906 Evaluation and grant award.

(a) Within the limits of funds available under section 782, the Secretary, after consultation with the Council, may award grants to those applicants whose projects will in his or her judgment best promote the purposes of section 782 of the Act, taking into consideration among other pertinent factors:

(1) The potential effectiveness of the proposed project in carrying out the purposes of § 57.2903(b).

(2) The reasonableness of the criteria for selection and enrollment of participants into the training program.

(3) The adequacy of the plan for identifying deficiencies in the medical education of the foreign medical students as required by § 57.2905 of this subpart.

(4) The adequacy of the proposed curriculum designed to correct these deficiencies.

(5) The administrative and managerial capability of the applicant to carry out the proposed project.

(6) The availability and adequacy of the resources available to the applicant to carry out the proposed project, including faculty, staff, equipment, and facilities.

(7) The qualifications of the project director.

(8) The reasonableness of the proposed budget in relation to the proposed project.

(9) The adequacy of the methods for monitoring and evaluating the performance of the foreign medical student participants, and of the overall project.

(b) The amount of any award will be determined by the Secretary on the basis of his or her estimate of the sum necessary for all or a designated portion of the direct costs of the project plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either (1) on the basis of his or her estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of this percentage will not exceed the approximate actual indirect costs. The award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limit of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) All grant awards will be in writing and will set forth the amount of funds granted and the period for which grant funds will be available for obligation by the grantee. The period of support for any grant under this subpart may not exceed 4 years.

(d) Neither the approval of any project nor the award of any grant commits or obligates the United States in any way to make any additional supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support grantees must make separate application at the time and in the form as the Secretary may require.

(e) If a grantee has filed an application for continuation support, and within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period for any previously approved project where the Secretary finds, on the basis of the progress and accounting reports as may be required, that the project's activities during the current budget period justify continued support for an additional budget period. If the Secretary determines to continue support, the amount of grant award will be determined in accordance with paragraph (b) of this section. If the Secretary determines not to continue a project for an additional budget period, The grantee will be notified in writing before the end of the current budget period. In addition if he or she determines that support is necessary, the Secretary may provide financial support for the orderly phase-out of the project.

§ 57.2907 Grant payments.

The Secretary will from time to time make payments to the grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the budget period or in advance for expenses to be incurred to the extent he or she determines payments are necessary to promote prompt initiation and advancement of the approved project.

§ 57.2908 Expenditure of grant funds.

(a) Funds granted under this subpart may be expended solely for carrying out the approved project in accordance with section 782 of the act the regulations of this subpart and the terms and conditions of the award. However, funds may not be expended for sectarian instruction or for any religious purpose.

(b) Funds granted under this subpart may be used to, among other things, identify deficiencies in the foreign medical education of foreign medical students, develop materials and methodology for correcting these deficiencies, and develop specialized training to prepare foreign medical students for enrollment in schools of medicine or osteopathy in the States as full-time students with advanced standing.

(c) Any unobligated grant funds remaining in the grant account at the close of a budget period may be carried forward and be available for obligation during subsequent budget periods of the project period. The amount of a subsequent award will take into consideration the amount remaining in the grant account. At the end of the last budget period of the project period, any unobligated grant funds remaining in the grant account must be refunded to the Federal Government.

§ 57.2909 Nondiscrimination.

(a) Recipients of grants under this subpart are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations are applicable:

(1) Section 704 of the act (42 U.S.C. 292d) and 45 CFR Part 83 (prohibiting discrimination on the basis of sex in the admission of individuals to training programs under title VII of the act);

(2) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.) and its implementing regulation, 45 CFR Part 80 (prohibiting discrimination in federally assisted programs on the grounds of race, color, or national origin);

(3) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) and its impementing regulation, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in federally assisted education programs); and

(4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and its implementing regulation, 45 CFR Part 84 (prohibiting discrimination in federally assisted programs on the basis of handicap).

(b) The grantee may not discriminate on the basis of religion in the admission of individuals to its training programs.

§ 57.2910 Grantee accountability.

(a) *Accounting for grant award payments.* The grantee must record all payments made by the Secretary in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee must account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart. When the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs will be computed on the basis of the predetermined fixed-percentage rates applied to the total or selected elements of the reimbursable direct costs incurred.

(b) *Accounting for copyright royalties.* Royalties received by grantees from copyrights on publications or other works developed under the grant must be accounted for as follows:

(1) Royalties received during the period of grant support may be retained by the grantee and, in accordance with the terms and conditions of the grant, used in either or both of the following ways:

(i) Used by the grantee for any purposes that further the objectives of section 782 of the act.

(ii) Deducted from the total project costs for the purpose of determining the net costs on which the Federal share of costs will be based.

(2) Royalties received after the completion or termination of grant support may be retained by the grantee unless the terms and conditions of the grant or a specific agreement negotiated between the Secretary and the grantee provide otherwise.

(c) *Grant closeout.* (1) *Date of final accounting.* A grantee must submit with respect to each approved project a full account, in accordance with this subpart, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* The grantee must pay to the Federal Government

as final settlement with respect to the approved project the total sum of (i) any amount not accounted for under paragraphs (a) and (b) of this section; and (ii) any other amounts due in accordance with Subparts F, M, and O of 45 CFR Part 74 and the terms and conditions of the grant award. This total sum constitutes a debt owed by the grantee to the Federal Government and is recoverable from the grantee or its successors or assigns by set off or other lawful action.

§ 57.2911 Publications and copyright.

The copyright policies set forth in 45 CFR 74.140 apply to grants made under this subpart.

§ 57.2912 Reports.

In addition to other reports as the Secretary may require, each school of medicine or osteopathy awarded a grant under this subpart during the fiscal year beginning October 1, 1977, and ending September 30, 1978, must submit to the Secretary before June 30, 1979, a report of any deficiencies identified in the foreign medical school education of foreign medical students who participated in the training project for which the grant was made. A draft copy of this report must be submitted to the Secretary by April 30, 1979.

§ 57.2913 Applicability of 45 CFR Part 74.

The relevant provisions of the following subparts of 45 CFR Part 74, establishing uniform administrative requirements and cost principles apply to all grants awarded under this subpart.

Subpart:
A General.
B Cash Depositories.
C Bonding and Insurance.
D Retention and Custodial Requirements for Records.
F Grant-Related Income.
G Matching and Cost Sharing.
K Grant Payment Requirements.
L Budget Revision Procedures.
M Grant Closeout, Suspension, and Termination.
O Property.
Q Cost Principles.

§ 57.2914 Records, audit, and inspection.

(a) *Records.* In addition to the applicable requirements of 45 CFR Part 74, the grantee must establish and maintain records as the Secretary may by regulation or order require, including records which completely disclose the amount and disposition of the total amount of funds received by the grantee for the project, the total cost of the project for which a grant was received, the total amount of that portion of the total cost of the project received by or allocated to the grantee from other sources, and other records as will facilitate an audit conducted in accordance with generally accepted auditing standards.

(b) *Audit.* The grantee is responsible for providing and paying for an annual financial audit of its books, accounts, financial records, files and other papers and property in accordance with the requirements of section 705(b) of the act. The audit must be conducted by and certified to be accurate by an independent certified public accountant utilizing generally accepted auditing standards. A report of the audit must be filed with the Secretary at the time and in the manner as the Secretary may require.

(c) *Inspection.* The grantee must make available to the Secretary or the Comptroller General of the United States or any of their duly authorized representatives all books, documents, papers, and records for examination, copying, or mechanical reproduction, on or off the premises of the grantee upon a reasonable request therefor.

§ 57.2915 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his or her judgment the conditions are necessary to assure or protect advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart EE—[Reserved]

Subpart FF—Grants for Residency Training in General Internal Medicine or General Pediatrics

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 784 of the Public Health Service Act, 90 Stat. 2315 (42 U.S.C. 295g-4).

SOURCE: 45 FR 51202, Aug. 1, 1980, unless otherwise noted.

§ 57.3101 To what projects do these regulations apply?

The regulations of this subpart apply to the award of grants under section 784 of the Public Health Service Act (42 U.S.C. 295g-4) to schools of medicine and osteopathy to meet the costs of projects (a) to plan, develop and operate approved residency training programs in internal medicine or pediatrics, which emphasize the training of residents for the practice of general internal medicine or general pediatrics and (b) which provide financial assistance (in the form of traineeships and fellowships) to residents who are participants in this type of program, and who plan to practice general internal medicine or general pediatrics.

§ 57.3102 Definitions.

For purposes of this subpart:

"Act" means the Public Health Service Act, as amended.

"Approved residency training program" or "program" is the entirety or that part of a residency training program which is fully or provisionally accredited by the Liaison Committee on Graduate Medical Education or approved by the American Osteopathic Association and which emphasizes the training of residents for the practice of general internal medicine or general pediatrics.

"Health manpower shortage area" means an area designated under section 332 of the Act.

"Nonprofit school" means a school no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

"Nurse practitioner" means a nurse practitioner as defined in 42 CFR 57.2402.

"Practice of general internal medicine or general pediatrics" means a practice which is limited to adult or child and adolescent medicine respectively, and in which the physician:

(1) Serves as physician of first contact with the patient and provides a timely means of entry into the health care system;

(2) Evaluates the patient's health needs, provides personal health care and refers the patient, if indicated, to appropriate sources of health care while preserving the continuity of care;

(3) Assumes with the patient responsibility for the patient's longitudinal and comprehensive (including preventive and psychosocial) health care and acts as coordinator of the provision of health services to the patient;

(4) Considers the patient's health care within the context of his or her environment including the community and family or comparable social units; and

(5) Where applicable, plans and shares the above functions with other physicians.

"Project director" means a fully licensed physician on the faculty of the grantee, designated by the grantee in the grant application and approved by the Secretary to direct the project being supported under this subpart.

"School of medicine or osteopathy" means a public or private nonprofit school which provides training leading respectively to a degree of doctor of medicine or to a degree of doctor of osteopathy and which is accredited as provided in section 772(b) of the Act.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department to whom the authority involved has been delegated.

"State" includes, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 57.3103 Who is eligible to apply for a grant?

Any school of medicine or osteopathy located in a State may apply for a grant under this subpart.

§ 57.3104 What activities must be addressed in an application?

In addition to other pertinent information which the Secretary may require, an application for a grant under this subpart must contain the following:

(a) A proposal for a project to plan, develop, and operate an approved residency training program or programs in internal medicine or pediatrics, or both (i) which emphasizes the training of residents for the practice of general internal medicine or general pediatrics, and (ii) which may provide financial assistance to residents who are participants in the program and who plan to practice general internal medicine or general pediatrics.

(b) A full and adequate description of the proposed project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart.

(c) A description of the resources to be used by the applicant for the conduct of the proposed project, including faculty, staff, equipment, facilities, and appropriate clinical practice settings (including those which are used to meet the requirements of § 57.3105(j) and (l)).

(d) A description of the type and amount of training to be offered to residents in each year of each residency program in accordance with the requirements of § 57.3105 with special attention to the requirements of § 57.3105(k).

(e) The number of residents to be enrolled in each program, at each level of training, for each year of the project period.

(f) A detailed budget for the proposed project and a justification of the amount of grant funds requested.

(g) Documentation showing that funds available from other sources will be insufficient to meet the costs of the project and that grant funds will not be used to supplant other available funds.

(h) If stipend support is requested by an applicant to provide a portion of the salary of residents enrolled in the program, documentation showing that income available from alternative sources, including income derived from the services of the residents in the program, will be insufficient to pay their salaries and that grant funds will not be used to supplant other available funds.

§ 57.3105 Project requirements.

For each residency program, a project must:

(a) Have a residency program director.

(b) Employ an individual with relevant experience or training who is responsible for curriculum development and evaluation.

(c) Employ faculty members experienced in the practice of general internal medicine or general pediatrics who participate as instructors at principal training settings.

(d) Employ individual(s) with formal education in behavioral sciences who participate in the preparation and implementation of the curriculum and in clinical consultation.

(e) Use a resident recruitment and selection process which assures that residents in the program have applied specifically for training in a program that emphasizes the practice of general internal medicine or general pediatrics.

(f) Provide financial assistance from grant funds only to residents who have signed statements of their intention to specialize or work in the practice of general internal medicine or general pediatrics.

(g) Have, in each program of a school of medicine, at least four residents in training by the beginning of the second year of Federal support, and at least 12 residents in training by the beginning of the fourth year of Federal support. By the beginning of the fourth year of Federal support, a program may meet this requirement with less than 12 residents in training if the number of internal medicine or pediatric residents in primary care training is at least 50 percent of the total number of internal medicine or pediatric residents at the institution. The Secretary may suspend this requirement for a period which he or she finds appropriate if the Secretary determines that a grantee has made a good faith effort to comply with the requirement and has met the other requirements of this Subpart and the Act, but is unable to have the required number of residents in the program due to circumstances beyond its control.

(h) Have, in each program of a school of osteopathy, at least two residents in training by the beginning of the second year of Federal support; and at least six residents in training in 3-year programs and at least four residents in training in 2-year programs by the beginning of the fourth year of Federal support. The Secretary may suspend any of these requirements for a period which he or she finds appropriate if the Secretary determines a grantee has made a good faith effort to comply with the requirement and has met the other requirements of this Subpart and the Act, but is unable to have the required number of residents in the program due to circumstances beyond its control.

(i) Plan to have residents distributed so that there is no decrease in numbers of residents in successive levels of training by the time the program is fully operational.

(j) Use one or more ambulatory care training settings which actively promote the practice of general internal medicine or general pediatrics, and which:

(1) Attract patients for primarily longitudinal and comprehensive (including psychosocial and preventive) health care;

(2) Organize personnel, including residents, into functional units providing comprehensive health services and provide residents with experience working with various types of health personnel;

(3) Have systems for referring patients to other specialists, and subspecialists, which assure coordination with the patients' own practitioners of general internal medicine or general pediatrics;

(4) Use an appointment system which facilitates the assignment of patients to their practitioner of general internal medicine or general pediatrics or to a particluar team of practitioners; and

(5) Use a medical record system which:

(i) Gives practitioners of general internal medicine or general pediatrics ready access to a patient's medical records including data relating to members of the patient's family which is pertinent to the patient's care;

(ii) Is suitable for audit by organizations or individuals who perform this work with adequate safeguards against unauthorized disclosures; and

(iii) Assures systematic review of the records.

(k) Make provision for each resident to serve a panel of patients and/or families who recognize him or her as their provider of longitudinal and comprehensive (including preventive and psychosocial) health care. The panel must be sufficiently numerous and varied to provide the resident with broad clinical experience. The clinical experience must be scheduled principally in ambulatory care settings as described in paragraph (j) of this section. A resident's time in these settings must:

(1) Comprise at least 10 percent of his or her total training time (excluding vacation time) during each year in the program (i.e., at least one-half day per week);

(2) Comprise at least 25 percent of his or her total training time (excluding vacation time) for the entire residency training period; and

(3) Be scheduled in at least nine months of each year of training.

(l) Offer ambulatory care training relevant to general internal medicine or general pediatrics in settings such as emergency rooms and specialty clinics.

(m) Have a planned curriculum which:

(1) Supplements the residents' inpatient and ambulatory patient care experiences with related educational activities such as courses, presentations, discussions, and reading assignments;

(2) Emphasizes subjects pertaining to:

(i) Ambulatory care;

(ii) Psychosocial skills and topics; and

(iii) Non-clinical areas relevant to the practitioner of general internal medicine or general pediatrics; and

(3) Is annually evaluated, using previously established criteria and objectives in a manner which includes the participation of residents.

(n) Develop and use systematic procedures to assess the individual resident's needs and to assist in educational planning and evaluation of the resident's competence.

§ 57.3106 How will applications be evaluated?

(a) After consulting with the National Advisory Council on Health Professions Education, established under section 702 of the Act, the Secretary will approve projects which will best promote the training purposes of section 784 of the Act. The Secretary will take into consideration, among other factors:

(1) The degree to which the proposed project adequately provides for the project requirements set forth in § 57.3105;

(2) The administrative and management capability of the applicant to carry out the proposed project in a cost-effective manner;

(3) The qualifications of the proposed staff and faculty;

(4) The potential of the project to continue on a self-sustaining basis.

(b) In determining the priority for funding of applications approved under paragraph (a) of this section, the Secretary will consider: (1) the relative merit of the proposed project based upon the factors in paragraph (a) of this section, and (2) the extent to which a proposed project contains any of the following elements:

(i) Substantial training experience in settings where physician assistants or nurse practitioners, or both, are used as part of a health care team.

(ii) Coordination of administrative and educational resources to be used by a program of general internal medicine and a program of general pediatrics which are both to be conducted within a single project.

(iii) Substantial portions of the project are conducted in a health manpower shortage area(s), and in particular, in a health manpower shortage area(s) which is located in a Standard Metropolitan Statistical Area, as defined by the Office of Federal Statistical Policy and Standards, Department of Commerce; or in an area health education center funded, at least in part, under section 781 of the Act.

§ 57.3107 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed five years.

(b) Generally, the grant will initially be funded for one year, and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental continuation or other award with respect to any approved application or portion of an approved application.

(d) Any balance of Federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 57.3108 How is the amount of the grant award determined?

The amount of any award will be limited to that portion of the annual program costs which the Secretary determines, on the basis of the documentation required in the application, cannot reasonably be paid from other available funds. Further, the amount of any stipend will be limited to that portion of the annual amount normally paid to other residents by the applicant which the Secretary determines, on the basis of the documentation required in the application, cannot reasonably be paid from other available funds, including the incomes derived by the hospital from the residents' services.

§ 57.3109 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

§ 57.3110 What additional Department regulations apply to grantees?

Several other regulations apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50—PHS grant appeals process

45 CFR Part 16—Department grant appeals process

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates and other cost allocations

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance from the Department—Implements Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally-assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in federally-assisted education programs

45 CFR Part 91[1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance

§ 57.3111 What other audit and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act concerning audit and inspection.

§ 57.3112 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart GG—Payment for Tuition and Other Educational Costs

Authority: Sec. 215, Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 711, Public Health Service Act, 90 Stat. 2253 (42 U.S.C. 292k).

Source: 45 FR 71568, Oct. 29, 1980, unless otherwise noted.

§ 57.3201 To which programs do these regulations apply?

The regulations in this subpart establish the criteria to be used in determining allowable increases in tuition and other educational costs for which the Secretary is responsible for payment under the following sections of the Public Health Service Act: The National Health Service Corps Scholarship Program (sec. 751) (42 U.S.C. 294t), the Indian Health Scholarship Program (sec. 757) (42 U.S.C. 294y-1), and Scholarships for First-Year Students of Exceptional Financial Need (sec. 758) (42 U.S.C. 294z). These programs are referred to herein as the "scholarship programs." The regulations apply to increases in tuition and other educational costs occurring after the school year beginning immediately before October 1, 1981.

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[1] When issued.

§ 57.3202 How will allowable increases be determined?

(a) The Secretary is responsible for increases in tuition and other educational costs only if the same increase is charged to all students in the same category (for example, the same class year or place of residence) and without regard to whether the student is receiving support under the scholarship programs. A student participating in the scholarship programs may not be denied eligibility because of this participation for any discounts or rebates in tuition or other educational costs given to all other students in the same category at the institution.

(b) Institutions whose enrollment contains 25 percent or more students participating in the scholarship programs, and whose percentage increase in tuition and other educational costs in any school year exceeds the previous calendar year's average inflation rate as indicated by the *Consumer Price Index for All Urban Areas,* may be requested to provide the Secretary with detailed cost breakdowns justifying the increase.

(c) In the case of a school which is requested to provide the Secretary with cost increase justification under paragraph (b) of this section, the Secretary will be responsible for increases in tuition and other educational costs charged to students participating in the scholarship programs over the amount charged for the school year immediately preceding the increase only to the extent that they are: (1) Attributable to uncontrollable costs, such as fuel costs, mandated cost-of-living increases in wages, salaries and fringe benefits, (2) attributable to costs of maintaining and improving the quality of the health professions education provided by the institution, such as hiring additional faculty to improve the faculty-student ratio, costs incurred in off-site training of students, and necessary improvements in teaching equipment. Increases in patient care and research costs are allowable as part of an increase in tuition and other educational costs only to the extent that they can be documented as clearly necessary to maintain and improve the quality of the education being supported; or (3) attributable to loss of revenue from other sources which was used solely for the maintenance and improvement of the educational system.

These three categories of valid escalators of tuition and other educational costs are exclusive. However, the examples *within* each category are merely illustrative and not meant to be inclusive.

(d) If the Secretary, after reviewing all available data, information, and justifications submitted by an institution, determines that an increase in tuition and other educational costs is not allowable under the criteria described in paragraph (a) or (c) of this section, the Secretary will provide the affected institution a detailed written explanation of the basis of that determination. The Secretary will be responsible for that portion of tuition and other educational costs the Secretary determines to be allowable.

Subpart HH—Programs for the Training of Expanded Function Dental Auxiliaries

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 701(8) of the Public Health Service Act, 90 Stat. 2247 (42 U.S.C. 292a(8)).

SOURCE: 44 FR 4479, Jan. 22, 1979, unless otherwise noted.

§ 57.3301 Purpose.

Section 701(8)(B) of the Public Health Service Act (42 U.S.C. 292a(8)(B)) requires the Secretary of Health and Human Services to prescribe regulations for programs for the training of expanded function dental auxiliaries. The purpose of this subpart is to comply with this requirement.

§ 57.3302 Definitions.

For purposes of this subpart:

"Academic year" means the approximately 9-12 month period of time during which the program is in session.

"Basic education program" means a dental assisting or dental hygiene education program accredited by the Commission on Accreditation of Dental and Dental Auxiliary Education Programs in which the existing course of study is modified to include additional preparation in expanded functions, preventive dentistry, and techniques to modify patient behavior.

"Dental assistant" means an individual who assists the dentist with the clinical, laboratory, or business operation of a dental practice and provides services to patients as may be delegated and supervised by the dentist in accordance with the law of the State in which the individual is employed.

"Dental auxiliary" means a dental assistant or dental hygienist.

"Dental hygienist" means an individual who is trained and licensed to provide preventive and therapeutic direct patient care services as may be delegated and supervised by the dentist in accordance with the law of the State in which the individual is employed.

"Expanded function dental auxiliaries" means dental assistants and dental hygienists who, by successfully completing a training program which meets the requirements of this subpart, are qualified to perform, under the supervision of a dentist, a new or wider range of clinical functions and direct patient care procedures.

"Four-handed, sit-down dentistry" means a mode of dental practice which encourages the efficient use of dental assistants and dental hygienists to assist the dentist or operating dental auxiliary in a manner that maximizes patient and operator comfort, saves time, and increases the potential productivity of the practice while maintaining the quality of dental care. This chairside assistance includes, but is not limited to, the following:

(1) Preparation for patient treatment;

(2) Chair positioning of patient, operator, and dental auxiliary;

(3) Use of prearranged sterilized instrument trays;

(4) Effective hand instrument exchange techniques;

(5) Standardized sequential usage of instruments;

(6) Use of water, air, and oral evacuation equipment to maintain a clear field of operations; and

(7) Preparation and delivery of restorative and other treatment materials required for the procedures.

"Full-time student" means a student who is enrolled in a program for the training of expanded function dental auxiliaries and pursuing a course of study which constitutes a full-time academic workload, as determined by the program.

"Preventive dentistry" means a method of practice and patient management that included a series of diagnostic, corrective, and disease preventive procedures, including patient education and motivation, that results in the establishment and maintenance of oral health in patients.

"Program director" means the individual responsible for providing competent direction of the program

"Supervised clinical practice" means direct participation by students in patient care by observation, examination, and performance of procedures as are appropriate for the assigned role of the student for the purposes of instruction, under the direction and responsibility of a licensed dentist who holds a faculty appointment at the institution conducting the program.

"Supplemental education program" means a program which provides training designed to extend the knowledge and skills of practicing dental auxiliaries so that they achieve clinical proficiency in expanded funtions, preventive dentistry, and techniques to modify patient behavior.

§ 57.3303 Requirements.

An education program which trains expanded function dental auxiliaries must:

(a) Be conducted by a school of dentistry or other public or nonprofit private entity accredited by the Commission on Accreditation of Dental and Dental Auxiliary Education Programs;

(b) Offer expanded function training in a basic education program or a supplemental education program, or both;

(c) Have an enrollment of not less than eight full-time students in each class;

(d) Be a minimum of one academic year in length;

(e) Consist of supervised clinical practice and at least four months (in the aggregate) of classroom instruction;

(f) Have a project director who is a full-time faculty member at the institution conducting the program;

(g) Have faculty who are qualified, through academic preparation and experience, to teach the subjects assigned and who are experienced in four-handed, sit-down dentistry;

(h) Have faculty for laboratory and clinical instruction who are competent in laboratory procedures and experienced in clinical practice;

(i) Have, in the supervised clinical practice sessions, a faculty-to-student ratio of one faculty member to no more than six students;

(j) Have adequate teaching facilities with sufficient space for instruction and practice in four-handed, sit-down dentistry techniques and expanded function procedures and be adequately equipped with functioning modern equipment;

(k) Have appropriate settings for the supervised clinical practice sessions which must be provided by the institution conducting the program or through written agreements with other institutions, agencies or organizations;

(l) Have adequate library, audiovisual, and other instructional resources;

(m) Before providing training in expanded functions, (1) require students to demonstrate clinical proficiency in the techniques of four-handed, sit-down dentistry or (2) train students to clinical proficiency in these techniques;

(n) Have a curriculum which provides for classroom instruction, preclinical laboratory instruction, and supervised clinical practice designed to train students to clinical proficiency in the performance of:

(1) At a minimum, all dental functions that may be delegated to dental auxiliaries under the law of the State in which the program is located; or

(2) In addition to the functions described in paragraph (n)(1) of this section, the expanded functions that may be taught by the program with the written concurrence of the Board of Dentistry of the State in which the program is located, for purposes such as preparing students for employment in other States or for national, regional, or other State credentialing.

(o) If is a supplemental education program, have entrance requirements for students, such as current certification or licensure, or require students to pass an entrance examination designed to determine whether they have the knowledge and skills necessary for achieving clinical proficiency in the performance of expanded functions;

(p) Have a plan and methodology for evaluating student performance, including:

(1) Standards for preclinical performance which students must meet before receiving clinical training; and

(2) Standards for evaluating the performance of expanded functions which are comparable to the standards used to evaluate the performance of the same skills by dental students; and

(q) Award a degree, diploma, or certificate of completion to individuals who have successfully completed the program.

Subpart II—Grants for Programs for the Training of Expanded Function Dental Auxiliaries

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 783(a)(2) of the Public Health Service Act, 90 Stat. 2314 (42 U.S.C. 295g-3(a)(2)).

SOURCE: 44 FR 4476, Jan. 22, 1979, unless otherwise noted.

§ 57.3401 To what projects do these regulations apply?

The regulations in this subpart are applicable to the award of grants to public or nonprofit private schools of dentistry and other public or nonprofit private entities under section 783(a)(2) of the Public Health Service

Act (42 U.S.C. 295g-3(a)(2)) to meet the costs of projects to plan, develop, and operate or maintain programs for the training of expanded function dental auxiliaries.

§ 57.3402 Definitions.

For purposes of this subpart:

"Act" means the Public Health Service Act.

"Budget period" means the interval of time into which the project period is divided for budgetary and reporting purposes, as specified in the grant award document.

"Council" means the National Advisory Council on Health Professions Education established by section 702 of the Act.

"Expanded function dental auxiliaries" means dental assistants and dental hygienists who, by successfully completing a training program which meets the requirements of Subpart HH, are qualified to perform, under the supervision of a dentist, a new or wider range of clinical functions and direct patient care procedures.

"Nonprofit" as applied to any school or entity means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures or may lawfully inure to the benefit of any shareholder or individual.

"Project director" means an individual designated by the grantee in the grant application and approved by the Secretary to direct the project being supported under this subpart.

"Project period" means the total time for which support for a project has been approved, including any extensions thereof.

"School of dentistry" means a school which provides training leading to a degree of doctor of dentistry or an equivalent degree and which is accredited as provided by section 772(b) of the Act.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

"Supervised clinical practice" means supervised clinical practice as defined in 42 CFR 57.3302(k).

§ 57.3403 What entities are eligible to apply for a grant?

(a) *Eligible applicants.* Any public or nonprofit private school of dentistry or other public or nonprofit private entity located in a State may apply for a grant under this subpart.

(b) *Eligible projects.* The Secretary may make grants under this subpart to eligible applicants for projects to plan, develop, and operate or maintain a program for the training of expanded function dental auxiliaries which meets the requirements of 42 CFR 57.3301-3303.

§ 57.3404 How must an entity apply for a grant?

(a) Each eligible applicant desiring a grant under this subpart must submit an application in the form and at the time as the Secretary may require.[1]

(b) The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations in this subpart.

(c) In addition to other pertinent information as the Secretary may require, an application for a grant under this subpart must contain a detailed description of the proposed project and of the manner in which the applicant intends to conduct the project and carry out the requirements of section 783 of the Act and this subpart, in particular, the requirements of § 57.3405. The application must include a budget for the proposed project and a justification for the amount of funds requested.

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[1] Applications and instructions may be obtained from the Grants Management Officer, Bureau of Health Manpower, Health Resources Administration, Center Building, Room 4-22, 3700 East-West Highway, Hyattsville, Md. 20782.

§ 57.3405 What requirements must a project meet?

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) The project must conduct its program for the training of expanded function dental auxiliaries in accordance with the requirements in 42 CFR 57.3301-3303.

(b) The project must be conducted under the direction of the project director. If the project director becomes unable to function in this capacity, the Secretary must be notified as soon as possible.

(c) In the case of a project to plan, develop, and operate a program for the training of expanded function dental auxiliaries, the planning and developmental activities must be accomplished within the first six months of the project period except that in the case of programs for which model curriculums, course materials, and expertise do not exist, the Secretary may approve a period of up to one year for planning and development.

(d) The project must develop and use appropriate methods for placing graduates of the program in dental assisting or dental hygiene positions for which they have been trained.

(e) In accordance with the plan set forth in its approved application, the project must collect, evaluate, and make available to the Secretary data concerning the program being conducted. This data collection and evaluation must include, at a minimum:

(1) Systematic evaluation by faculty and students of the program curriculum in relation to the purposes, objectives, and conceptual framework of the program;

(2) Evaluation of the effectiveness of the program in relation to its purposes and objectives;

(3) Information concerning the number of student applicants and students enrolled, and student characteristics (such as age, sex, race, educational background, and previous work experience, including type of position, specialty, and work setting); and

(4) Information concerning the number of graduates per class, the attrition rate, characteristics of graduates, and use and performance of graduates (including employer assessment).

(f) At the time and in the manner the Secretary requires, the project must participate in a program conducted by the Secretary to evaluate the overall effectiveness of Federal support for the training of expanded function dental auxiliaries.

§ 57.3406 How will the Secretary evaluate applications and make grant awards?

(a) *General.* (1) Within the limits of funds available for this purpose the Secretary, after consultation with the Council, may award grants to those applicants whose projects will in his or her judgment best promote the purposes of section 783(a)(2) of the Act, taking into consideration:

(i) The degree to which the project plan adequately provides for meeting the requirements in § 57.3405.

(ii) The number of students the project proposes to train in the program.

(iii) The scope and skill level of expanded functions which the project proposes to teach in the program.

(iv) The potential effectiveness of the project in carrying out the training purposes of section 783(a)(2) of the Act.

(v) The administrative and managerial capability of the applicant to carry out the project.

(vi) The adequacy of the facilities and resources available to the applicant to carry out the project.

(vii) The qualifications of the project director and faculty.

(viii) The reasonableness of the proposed budget.

(ix) The potential of the project to continue on a self-sustaining basis after the project period.

(2) The Secretary will give special consideration to:

(i) Projects designed to train students to clinical proficiency in the greatest number of expanded functions which increase the productivity of the dental team, including advanced skills.

(ii) Projects designed to provide students with opportunities for training in locations geographically remote from the main site of the teaching facilities of the program.

(iii) Projects designed to provide students with opportunities for interdisciplinary or team training experiences.

(3) All grant awards will be made in writing and will set forth the amount of funds granted and the period for which funds will be available for obligation by the grantee.

(4) Except as provided in paragraph (a)(5) of this section, projects receiving grants under this subpart may be approved for an initial project period of up to three years. Grantees may apply for up to two years of additional support by submitting a competing extension application.

(5) Projects maintaining programs, for the training of expanded function dental auxiliaries, supported under this subpart and which previously received support under section 774(a) of the Act, as in effect on September 30, 1977, may receive grants to maintain their programs for no more than the period of time which, when added to the period of support under section 774(a), equals five years.

(6) Neither the approval of any project nor the award of any grant commits or obligates the United States in any way to make additional supplemental, continuation, or other awards with respect to any approved project or any portion of an approved project. For continuation support, grantees must make separate application at the time and in the form which the Secretary requires.

(b) The Secretary will determine the amount of an award on the basis of his or her estimate of the sum necessary for the direct and indirect costs of the project. In the case of projects whose periods of support, including any periods of support received under section 774(a) of the Act as in effect on September 30, 1977, exceed three years, however, the amount of the fourth year of support may not exceed 60 percent of the award for the third year of support and the amount of the fifth year of support may not exceed 40 percent of the award for the third year of support.

(c) The Secretary may make a grant award for an additional budget period for any previously approved project on the basis of an application and those progress and accounting records which may be required. If the Secretary finds that the project's activities during the current budget period justify continued support, and the Secretary decides to continue support, the amount of the grant award will be determined in accordance with paragraph (b) of this section.

§ 57.3407 How will grant payments be made?

The Secretary will, from time to time, make payments to a grantee of all or a portion of any grant award either in advance or by way of reimbursement.

§ 57.3408 Purposes for which grant funds may be spent.

(a) Funds granted under this subpart may be expended solely for carrying out the approved project in accordance with section 783(a)(2) of the Act, the regulations of this subpart and the terms and conditions of the award. Funds may not be expended for sectarian instruction or for any religious purposes.

(b) Funds granted under this subpart may be used in accordance with an approved application for the clinical training of dental assistant and dental hygienist faculty members to teach in the program conducted by the project.

(c) The amount of funds granted under this subpart which may be used for alteration and renovation of facilities during the project period may not exceed the lesser of $10,000 or 25 percent of the total funds recommended for direct costs for the project period.

(d) Any unobligated grant funds remaining in the grant account at the close of a budget period may be carried forward and be available for obligation during subsequent budget periods of the project period. The amount of the subsequent award will take into consideration the amount remaining in the grant account.

(e) Grant funds may not be used for sectarian instruction or for any other religious purpose.

§ 57.3409 What nondiscrimination requirements apply to grantees?

(a) Recipients of grants under this subpart are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations are applicable:

(1) Section 704 of the Act (42 U.S.C. 292d) and its implementing regulation, 45 CFR Part 83 (prohibiting discrimination on the basis of sex in the admission of individuals to training programs);

(2) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its implementing regulations, 45 CFR Part 80 (prohibiting discrimination in federally assisted programs on the ground of race, color, or national origin);

(3) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) and its implementing regulation, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in federally assisted education programs); and

(4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and its implementing regulation, 45 CFR part 84 (prohibiting discrimination in federally assisted programs on the basis of handicap.)

(b) The grantee may not discriminate on the basis of religion in the admission of individuals to its training programs.

§ 57.3410 How must grantees account for grant funds received?

(a) *Accounting for grant award payments.* The grantee must record all payments made by the Secretary in accounting records separate from the records of all other funds, including funds derived from other grant awards. The grantee must account for the sum total of all amounts paid by presenting or otherwise making available, evidence satisfactory to the Secretary of funds spent for costs meeting the requirements of this subpart.

(b) Grant closeout.

(1) Date of final accounting. The grantee must submit, with respect to each grant under this subpart, a full account, in accordance with this subpart, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) Final settlement. The grantee must pay to the Federal Government as final settlement with respect to each grant under this subpart the total sum of (i) any amount not accounted for under paragraphs (a) and (b) of this section and (ii) any other amounts due in accordance with 45 CFR Part 74 and the terms and conditions of the grant award. This total sum constitutes a debt owed by the grantee to the Federal Government and is recoverable from the grantee or its successors or assigns by setoff or other lawful action.

§ 57.3411 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, apply to all grants under this subpart.

§ 57.3412 What recordkeeping, audit, and inspection requirements apply to grantees?

Each school which receives a grant under this subpart must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act, concerning recordkeeping, audit, and inspection.

§ 57.3413 What additional conditions apply to grantees?

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his or her judgment these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart JJ—Grants to Schools of Medicine, Osteopathy, Dentistry, Public Health, Veterinary Medicine, Optometry, Pharmacy, and Podiatry for Support of Their Education Programs

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216) secs. 770-72 of the Public Health Service Act, 90 Stat. 2290 as amended by 91 Stat. 391 and 1503, 92 Stat. 3456 and 3457 (42 U.S.C. 295f).

SOURCE: 45 FR 51206, Aug. 1, 1980, unless otherwise noted.

§ 57.3501 To whom do these regulations apply?

The regulations in this subpart apply to the award of annual grants to schools of medicine, osteopathy, dentistry, public health, veterinary medicine, optometry, pharmacy, and podiatry for the support of the educational programs of these schools.

§ 57.3502 Definitions.

"Act" means the Public Health Service Act, as amended.

"Ambulatory care setting" means a facility in which health care is delivered to persons who are ambulatory and who are not patients in a hospital or other inpatient care facility for the purpose of receiving the particular care being provided.

"Construction" means (a) the construction of new buildings or the expansion or acquisition of existing buildings (including related costs such as architects' fees, acquisition of land, offsite improvements, and the initial equipping of buildings); and (b) the remodeling, alteration and repair of existing buildings.

"Council" means the National Advisory Council on Health Professions Education established by section 702 of the Act.

"Dental specialty program" means a program in any dental specialty which is accredited by a body or bodies recognized for this purpose by the Secretary of Education and is at least one academic year in length. For purposes of this subpart a residency training program in the general practice of dentistry is considered a dental specialty.

"Fiscal year" means the Federal fiscal year beginning October 1 and ending the following September 30.

"Full-time course of study" means a course of study in which the student is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters or other academic terms normally required to complete the course of study on a full-time basis.

"Full-time student" means a student as defined in section 770(c) of the Act.

"Medically underserved population" means a population group designated under section 332(b) of the Act, a population group served by a facility designated under that section, or a population group residing in an area designated under that section.

"Resident of a State" means one who was residing in that State at the time of his or her application to the school.

"School" means a public or other nonprofit school of medicine, osteopathy, dentistry, public health, veterinary medicine, optometry, pharmacy, and podiatry as defined in section 701(4) of the Act and which is accredited as provided in section 772(b) of the Act.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department to whom the authority involved has been delegated.

"State" means, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 57.3503 Who is eligible to apply for a health professions capitation grant?

Any school which is located in a State may apply for a grant under this subpart.

§ 57.3504 What assurances are required of all applicants for capitation grants?

In accordance with the requirements of section 771(a) of the Act, each school must furnish reasonable assurances satisfactory to the Secretary that:

(a) The first-year enrollment of full-time students in the school, in the school year beginning in the fiscal year in which the grant applied for is to be made, will not be less than the first-year enrollment of full-time students in the school in the preceding school year or in the school year which began in the fiscal year ending

September 30, 1976, whichever is greater.

(b) The applicant will spend an amount of funds from non-Federal sources (other than funds for construction) in carrying out its functions as a school during the fiscal year for which the grant is sought, which is at least as great as the amount of funds spent by the applicant for this purpose (excluding expenses of a nonrecurring nature) in the fiscal year preceding the fiscal year for which the grant is made.

§ 57.3505 What additional requirements apply to schools of medicine?

Medical residency training program requirements: Under section 771(b)(2) of the Act (42 U.S.C. 295f-1(b)(2)), the Secretary must determine as of July 15 of each year, the percentage of filled first year positions in direct or affiliated medical residency training programs that are filled first year positions in primary care in all schools in the States. If the percentage for all schools nationwide is not 50 percent on July 15, each individual school of medicine, in order to be eligible for a grant, must have on July 15 of the following year at least 50 percent of its filled first year positions in its direct or affiliated medical residency training programs in filled first year positions in primary care. The Secretary will publish a notice in the FEDERAL REGISTER announcing the results of his or her annual determination and whether individual schools will be required to comply with the provisions of this paragraph.

(a) For the purpose of making this determination:

(1) "Medical residency training program" means a medical residency training program which is approved or provisionally approved by the Liaison Committee on Graduate Medical Education.

(2) "Direct or affiliated medical residency training program" means a medical residency training program conducted in facilities owned by the applicant school or its parent organization or a medical residency training program which has an arrangement with the school or one of the school's constituent units, providing for any of the following:

(i) The exchange of three or more students enrolled in the school of medicine for a total of at least 12 months of education within any given school year; or any exchange of at least one medical resident for at least one year; or

(ii) The exchange of faculty between the school of medicine or one of its constituent units and the residency program; or the appointment to any faculty position at the school of medicine of any individual on the staff of the entity sponsoring the residency program who has any responsibility for the program (term "faculty" excludes individuals who receive no financial compensation for their teaching activities or who have no responsibility for the instruction of students or residents in the medical residency training program); or

(iii) The provision or receipt by the school of medicine or one of its constituent units of any funds for the residency program.

(3) "Filled first-year position" means any filled position in:

(i) The first year of a medical residency training program sponsored by a residency program in family practice, internal medicine, pedistrics, obstetrics and gynecology, pathology or general surgery;

(ii) The first year of medical residency training program jointly sponsored by two or more medical residency training programs, or

(iii) Any position in any other type of medical residency training program in which a resident is enrolled in his or her first year of graduate medical education.

(4) "Filled first-year position in primary care" means all filled positions in·

(i) The first year of medical residency training program sponsored by a residency program in family practice, internal medicine or pediatrics; and

(ii) The first year of medical residency training programs jointly sponsored by any combination of residency programs in family practice, internal medicine, or pediatrics.

§ 57.3506 What additional requirements apply to schools of osteopathy?

Each school of osteopathy must also submit, or participate in the joint submission of, a plan for the Secretary's approval to train full-time students in ambulatory care settings either in areas geographically remote from the main site of the teaching facilities of the applicant school or schools, or in areas in which medically underserved populations reside. An ambulatory care setting is considered to be geographically remote if it is physcially removed from the facility or facilities where the major part of the educational program of the school is conducted and should, to the maximum extent feasible, be located in areas in which medically underserved populations reside. The training must occur in the school year beginning in the fiscal year for which the grant is made and in each subsequent school year for which a grant is made. In the case of a joint submission of a plan by two or more schools, the plan must detail the specific responsibilities of each school submitting the plan, and must be signed by an authorized official of each school. In addition, each grantee must provide evidence of adequate progress in implemening the plan approved in the fiscal year immediately preceding the year of re-application.

§ 57.3507 What additional requirements apply to schools of dentistry?

(a) Each school of dentistry must also meet the requirements of section 771(d)(2) of the Act and, at the option of the school of dentistry, the requirements of either section 771(d)(3) or section 771(d)(4) of the Act. Where a school elects to meet the requirements of section 771(d)(4) of the Act, the school must submit, or participate in the joint submission of, a plan for the Secretary's approval to train full-time students in ambulatory care settings either in areas geographically remote from the main site of the teaching facilities of the school or in areas in which a medically underserved population resides. An ambulatory care setting is considered to be geographically remote if it is physically removed from the facility or facilities where the major part of the educational program of the school is conducted and should to the maximum extent feasible be located in areas in which there is a need for dentists. The clinical training must occur in a health care delivery setting which enables the student, under practitioner-instructor supervision, to integrate and assume the roles, functions, and responsibilities that characterize a dental practitioner and that trains the student to provide primary dental care.

(b) The Secretary may waive requirements for a school of dentistry under section 771(d) of the Act if the Secretary determines, after receiving the written recommendation of the appropriate accreditation body or bodies approved for this purpose by the Secretary of Education, that compliance with the requirements would prevent the school from maintaining accreditation.

(c) The Secretary may, in the case of a school of dentistry which increased its enrollment of full-time first-year students in accordance with section 771(d)(3) of the Act, waive (in whole or in part and under such conditions as the Secretary may prescribe) application of the requirement of subsection 771(a)(1) of the Act that it maintain its increased enrollment of such students.

§ 57.3508 What additional requirements apply to schools of public health?

Each school of public health must also meet the requirements of section 771(e)(1) of the Act with respect to increasing its enrollment of full-time first-year students.

§ 57.3509 What additional requirements apply to schools of veterinary medicine?

Each school of veterinary medicine must also meet the requirements of section 771(f)(2) and, at the option of the school of veterinary medicine, either section 771(f)(3) or section 771(f)(4) of the Act. A school of veterinary medicine will meet the requirements of section 771(f)(2) of the Act relating to emphasizing care to food-producing or fiber-producing animals if over 50 percent of the total credits or contact hours of both the clinical aspects of the basic biomedical sciences and the clinical care training programs consist of treating food-producing and/or fiber-producing animals.

§ 57.3510 What additional requirements apply to schools of optometry?

A school of optometry must also meet the requirements of either section 771(g)(2) or section 771(g)(3) of the Act at the option of the school of optometry.

§ 57.3511 What additional requirements apply to schools of podiatry?

A school of optometry must also meet the requirements of either section 771(h)(2) or section 771(h)(3) of the Act at the option of the school of podiatry.

§ 57.3512 What additional requirements apply to schools of pharmacy?

A school of pharmacy must also meet the requirements of section 771(i) of the Act.

§ 57.3513 How will the number of students at each school be determined?

(a) The number of full-time students enrolled in a school, or the number of full-time, first-year students enrolled in a school, for any year, will be the number of students enrolled in the school on September 15 of the fiscal year in which the grant is made except that in the case of a school of pharmacy or school of medicine with a course of study of more than 4 years; (1) full-time students mean only those students enrolled in the last four years of the school, and (2) full-time first-year students mean those students enrolled in the first of the last four years. The Secretary may, upon application, approve a date other than September 15 as the official counting date for schools whose academic calendars make the September 15 date inappropriate.

(b) The classification of a full-time student as a first-year student will be in accordance with the policies of the particular school, except that for the purpose of the assurances required by section 771 of the Act:

(1) A student may not be counted as a first-year student more than once, except that a student who, for other than academic reasons, withdraws from a year class before the end of an academic year or does not complete an academic year shall not be considered as having been enrolled in a year class in that academic year.

(2) A first-year student enrolled in a school of public health is one who is enrolled in the first year of a course of study leading to a master's degree or in the first year of a course of study leading to a doctoral degree for which no post-baccalaureate studies are a prerequisite for admission into the program.

§ 57.3514 Under what circumstances and in what amounts may these grants be made?

(a) The Secretary will award a capitation grant to each applicant whose application is found by the Secretary, after consultation with the Council, to meet the requirements of the applicable provisions of the Act and of this subpart.

(b) The amount of each capitation grant will be an amount computed in accordance with the formula set forth in section 770(a) of the Act. If the amount of funds appropriated under section 770(e) of the Act for any category of health professions schools for any fiscal year is less than the total of the amounts so computed for each school in that category with an approved application, the grant awarded to each such school will be reduced proportionately in accordance with section 770(b) of the Act.

§ 57.3515 What expenses are allowable under these capitation grants?

(a) Capitation grant funds may be obligated by the school at any time before the end of the 24-month period specified in the grant award document for any purpose related to the educational program of the school, except as otherwise provided in paragraph (b) of this section. Any funds not obligated must be refunded to the Federal Government.

(b) Capitation grant funds may not be expended for the following purposes:

(1) Construction, except that grant funds may be used for remodeling, alteration and repair of existing buildings;

(2) Student assistance; or

(3) Sectarian instruction or any religious purpose.

§ 57.3516 What additional Department regulations apply to grantees?

Several other regulations apply to these grants. They include, but are not limited to:

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of Grants

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department-Implementation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs

45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in Federally assisted education programs

45 CFR Part 91[1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance.

§ 57.3517 What audit inspection, and reporting requirements apply to grantees?

(a) Each school which receives a capitation grant must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act, concerning audit and inspection.

(b) Each school which receives a capitation grant must meet the requirements of section 708(c) of the Act, concerning reporting information on students who attend the school.

§ 57.3518 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of any award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of funds.

Subparts KK–LL—[Reserved]

Subpart MM—Area Health Education Center Program

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); Sec. 781 of the Public Health Service Act, 90 Stat. 2312 (42 U.S.C. 295g-1).

SOURCE: 43 FR 55244, Nov. 27, 1978, unless otherwise noted.

§ 57.3801 To what programs do these regulations apply?

The regulations of this subpart apply to the award of contracts under section 781 of the Public Health Service Act (42 U.S.C. 295g-1) to medical and osteopathic schools for the planning, development, and operation of area health education center programs.

§ 57.3802 Definitions

As used in this subpart:

"Act" means the Public Health Service Act.

"Allied health personnel" means individuals as defined in 42 CFR 58.502.

"Area health education center" or "center" means a public or nonprofit private entity which has a cooperative arrangement with one or more schools of medicine or osteopathy for the planning, development, and operation of an area health education center program. A center must be an entity which is recognized under the laws of the State in which it is located and which has as one of its principal functions the operation of the area health education center.

"Area health education center program" or "program" means a cooperative program among one or more schools of medicine or osteopathy and one or more area health education centers, which is capable of performing the functions described in sections 781(c) and (d)(2) of the Act and § 57.3805 of these regulations, and which is designed to improve the distribution, supply, quality, utilization, and efficiency of health personnel in the health services delivery system and to encourage the regionalization of educational responsibilities of health professions schools.

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[1] When issued.

"Clerkship" means supervised clinical training.

"Continuing medical education" or "continuing education" means any education for the purpose of maintaining or enhancing the knowledge, attitudes or abilities of a health professional in his or her field which does not lead to any formal advanced standing in the profession.

"Health professional" means any physician, dentist, optometrist, podiatrist, pharmacist, nurse, nurse practitioner, physician's assistant or allied health personnel.

"Nurse practitioner" means an individual as defined in 42 CFR 57.2402.

"Physician's assistant" means an individual as defined in 42 CFR 57.802.

"Preceptorship" means an educational experience in which the student works with a designated health professional, the preceptor, who teaches in the student's field of study and personally supervises the student's clinical activity.

"School of medicine, osteopathy, dentistry, optometry, podiatry, pharmacy, public health or veterinary medicine" means a school as defined in section 701(4) of the Act which is accredited as provided in section 772(b) of the Act.

"School of nursing" means collegiate, associate degree or diploma school of nursing as defined in section 853 of the Act.

"Training center for allied health professions" means a training center as defined in 42 CFR 58.402.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

§ 57.3803 What entities are eligible to submit proposals?

(a) Any public or nonprofit private school of medicine or osteopathy located in a State is eligible to submit a proposal.

(b) More than one school of medicine or osteopathy may submit a joint proposal for the planning, development and operation of an area health education center program. In this case each school must conduct the activities required by section 781(c) of the Act and § 57.3805(d).

§ 57.3804 How are proposals submitted?

Proposals for contracts under this subpart must be submitted in the form and manner and at the time which the Secretary may prescribe in the Request for Proposals.

§ 57.3805 What requirements apply to projects?

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) Each area health education center program must have a program director who holds a faculty appointment at a medical or osteopathic school participating in the program and who is responsible for the overall direction and coordination of the program.

(b) Each area health education center program must have a program advisory committee to advise the program director on all aspects of the conduct of the program, including administrative, education and evaluation. This committee must include representatives of schools and programs of health professions which actively participate in the area health education program under § 57.3805(d)(5) of this subpart and section 781(c)(4) of the Act, individuals with training and experience in the fields of: medicine or osteopathy, dentistry, nursing, and an allied health profession, as well as a representative of each of the centers cooperating in the program.

(c) Each area health education center program must annually evaluate its activities to ascertain the extent to which it is meeting the purposes described in section 781(a) of the Act.

(d) *Requirements for schools of medicine or osteopathy.* A school of medicine or osteopathy participating in an area health education program (with the exception of a school whose only function is to provide resources by purchase agreement to a center) must:

(1) Have a cooperative arrangement with an area health education center, as evidenced by a written agreement. This agreement must provide at a minimum that the schools participating in the program will perform the following functions:

(i) Provide faculty to assist in the conduct of the center's educational activities, as necessary;

(ii) Provide an agreed upon amount of funds to the center to assist the center in meeting the costs of its activities, including those described in section 781(d)(2) of the Act;

(iii) Be responsible for the quality of the education received in the center, including evaluating the quality of the educational programs required by section 781(d)(2) of the Act and the performance of its students while receiving clinical training in the center. The area health education center must agree to conduct the activities described in section 781(d)(2) of the Act and these regulations and assist the schools participating in the program in meeting the requirements in section 781(c) of the Act and these regulations.

(2) Provide for the active participation in the program by individuals who are associated with the administration of the school, and staff or faculty members of each of the departments (or specialties if the school has no departments) of internal medicine, pediatrics, obstetrics and gynecology, surgery, psychiatry and family medicine. These persons may participate in the program in either the school or center and must perform, among others, the following functions: provide guidance on educational program or curriculum development and operation; instruct students (including residents and other practicing health professionals); perform student or program evaluation; and assist in program administration.

(3) Conduct no less than 10 percent of all undergraduate medical or osteopathic clinical education of the school in one or more centers and in clinical settings which are part of or affiliated with a center and in which the center arranges and supports the clinical education. The school shall assure that, annually the ratio of student-weeks of clinical education received by its undergraduate students in centers to the total number of student weeks of clinical education received by its undergraduate students, in any location, is no less than 0.10. For purposes of this paragraph, undergraduate medical or osteopathic clinical education means any clerkships, preceptorships, or other educational activities which are offered in the following fields: family medicine, internal medicine and its subspecialties, pediatrics and its subspecialties, dermatology, obstetrics and gynecology, surgery and its subspecialties, anesthesiology, psychiatry and its subspecialties, neurology, physical medicine and rehabilitation, emergency medicine, nuclear medicine and general preventive medicine, including community medicine. Courses, seminars, and other educaional programs which are entirely didactic or laboratory in nature or which are primarily in anatomy, biochemistry, physiology, microbiology, pharmacology, or pathology are not include in this definition.

(4) Be responsible for, or conduct a program for the training of physician's assistants, which meets the requirements of 42 CFR Part 57, Subpart I, or nurse practitioners, which meets the requirements of 42 CFR Part 57, Subpart Y Appendix. Where the school is responsible for but does not conduct one of these programs, it must participate in the presentation, review, and evaluation of one of these programs at an affiliated institution so that at least part of the education in the program is provided by faculty of the school. The school must give special consideration to the enrollment in these programs of individuals from or who plan to practice in the area served by the center by either:

(i) Giving preference to applicants whose place of residence has been in the area served by the center at any time prior to application; or

(ii) Obtaining a signed statement from applicants, indicating an intent to practice the skills acquired in the program in the area.

(5) Provide for the active participation of at least two schools or programs of other health professions in the educational program conducted in

the area served by the center(s). In meeting this requirement:

(i) One of the participating schools or programs must be a school of dentistry, if there is one affiliated with the university with which the school of medicine or osteopathy is affiliated;

(ii) Only the following schools or programs of other health professions may be included to meet the requirement of this paragraph:

(A) Training centers for the allied health professions;

(B) Schools of nursing;

(C) Schools of optometry;

(D) Schools of pharmacy;

(E) Schools of podiatry; or

(F) Schools of public health.

(iii) Each school or program participating in the area health education center program under this paragraph must have a written agreement with the school(s) of medicine or osteopathy, under which the school or program agrees to assist and participate, as is appropriate, in the activities of each center as required under section 781(d)(2) of the Act.

(iv) Each school or program participating in the area health education center under this paragraph must have a written agreement with each center, under which the school or program agrees to provide some or all of its students with educational experiences in the center or in settings affiliated with the center, and the center agrees to arrange for and support the provision of the educational programs. This agreement may be part of the agreement required by paragraph (d)(1) of this section.

(e) *Requirements for area health education centers:*

Each area health education center participating in an area health education center program must:

(1) Designate either a geographic area or medically underserved population which it will serve ("the area served by the center"). This area or population must be in a location remote from the main site of the teaching facilities of the schools which participate in the program. For purposes of this requirement,

(i) A medically underserved population means the population of a geographic area designated as a primary medical manpower shortage area under section 332 of the Act or a population group designated under section 332 of the Act as having a shortage of primary medical care manpower.

(ii) An area or population will meet this requirement if its location is removed from the site of the teaching facilities where the major part of the educational program of any participating schools is conducted. The area served by the center must not duplicate, in whole or in part, the area served by any other center.

(2) Provide for or conduct training in health education services, in the area served by the center. This training must consist of courses and programs to train health professionals to instruct the public or patients in medical self-help, disease prevention, accident prevention, nutrition, physical fitness, and other subjects relating to health maintenance, and must include the principles of nutrition, the evaluation of nutritional status, and nutritional counseling. The training must be oriented towards the ethnic and cultural backgrounds of the people in the area.

(3) Assess the health manpower needs of the area served by the center and assist in the planning and development of training programs to meet these needs. In meeting this requirement the center must cooperate with the health systems agencies designated for the area served by the center and other appropriate entities in determining data on health manpower needs of the area for the next 10 years and in developing a plan for training programs to meet these needs. At a minimum the center must assess the need for (i) manpower to provide health education and nutrition counseling services, (ii) primary care health manpower including physicians in family practice, general internal medicine, general pediatrics, and obstetrics and gynecology, physican's assistants, and nurse practitioners; (iii) mental health practitioners, (iv) dentists and (v) nurses. In carrying out its responsibility to assess health manpower needs in the area, the center shall, to the maximum extent practicable, use existing data (including data used for the designation of shortage areas

under sections 332 and 836(h) of the Act).

(4) Provide for or conduct a medical residency training program in family practice, general internal medicine, or general pediatrics in which no fewer than six persons are enrolled in first-year positions in the program. If one center which is participating in the area health education center program provides for or conducts a medical residency training program meeting this requirement, other centers participating in the program may, but need not, provide for or conduct a medical residency training program in these fields. In meeting this requirement:

(i) A family practice residency must meet the requirements of section 786(a) of the Act, and implementing regulations.

(ii) A general internal medicine or general pediatrics residency must meet the requirements of 42 CFR § 57.3105, except for the requirements in paragraphs (h) and (i) of that section.

(iii) The center must conduct the medical residency training program at a site which is part of the center or provide for the conduct of this program, by written affiliation agreement with an appropriate entity located in the area served by the center.

(5) Provide opportunities for continuing medical education (including education in disease prevention) to all physicians and other health professionals practicing within the area served by the center. This continuing medical education must include courses, seminars, lectures, grand rounds, clinical pathological conferences, mini-residencies, library services, or in-house training, as appropriate for all health professionals in the area. In meeting this requirement:

(i) The center must assess the need for providing continuing medical education taking into consideration the numbers, needs and location of health professionals in the area as well as educational activities available through other entities.

(ii) The center must announce the availability of continuing medical education activities offered in the center as well as those provided through other entities and distribute these announcements to all health professionals in the area.

(6) Provide continuing medical education and other support services to the National Health Service Corps (Corps) members assigned to the area served by the center, after notification of the assignment(s) by the Secretary. In meeting this requirement the center must:

(i) Establish an organized program which will provide for the assessment of the continuing medical education needs of the members of the Corps and offer to members of the Corps, at a cost not to exceed the cost to any other participant, continuing medical education relevant to these identified needs.

(ii) Assist in providing

(A) Consultation services, if needed, including telephone consultation, to Corps personnel.

(B) A patient referral system, if necessary, to Corps patients and assistance to these patients in obtaining laboratory and pathological services, at accessible locations.

(C) Supervision and consultation for non-physician and non-dentist members of the Corps in the area.

(D) Temporary substitutes for Corps personnel, as needed.

(7) Encourage the utilization of nurse practicioners and physician's assistants in the area and the recruitment of individuals for training in these professions at the participating medical or osteopathic schools. In meeting this requirement, the center must:

(i) Inform potential employers in the area regarding the following, among other subjects:

(A) The function and utilization of nurse practitioners and physician's assistants;

(B) State laws and regulations governing nurse practitioners and physician's assistants; and

(C) Reimbursement and malpractice coverage for services rendered by nurse practitioners and physician's assistants.

(ii) Determine employment opportunities for nurse practitioners and physician's assistants and participate in referral and recruitment of persons for these positions.

(iii) Distribute information in the area concerning the nurse practitioner or physician's assistant training program(s) provided for or conducted by the schools of medicine or osteopathy participating in the program, and participate in recruiting persons in the area for the programs.

(8) Arrange and support educational opportunities for medical and other students at affiliated health facilities, ambulatory care centers, and health agencies throughout the area served by the center. In meeting this requirement, the center must:

(i) Coordinate the conduct of the following programs, including assisting in their planning and development, obtaining the necessary resources and providing administrative support services for:

(A) Clinical education for undergraduate medical or osteopathic students in at least family practice, general internal medicine and general pediatrics;

(B) Education for undergraduate and, as appropiate, graduate students, at a school of dentistry, if one is participating in the program;

(C) Education for students of the other schools or programs participating in the area health education center program under § 57.3805(d)(5); and

(D) Orientation for high school and post-high school students in schools in the area to develop awareness of health careers and health opportunities.

(9) Have an advisory board of which at least 75 percent of the members are persons from the area served by the center, including health service providers and consumers. For this purpose, health service providers are individuals who derive more than 10 percent of their annual income from the health care industry. In meeting this requirement:

(i) The advisory board must be reasonably divided between:

(A) Providers of health care, including at least one physician, dentist, nurse, and allied health professional, who is actively engaged in the practice of his or her profession in the area served by the center; and

(B) Consumers, including students, who reside in the area and are broadly representative of the population in the area in terms of demographic factors, such as race, ethnic background, and sex. The advisory board shall advise the chief administrative official of the center on all major policies concerning the operation of the center, on the establishment of center program priorities and on other issues, as necessary.

§ 57.3806 When do the requirements of § 57.3805 apply? [1]

(a) The period of time in which any entity will have to meet all the requirements of § 57.3805 will be negotiated on a case-by-case basis depending upon the nature and scope of the planned area health education center program. No contract, however, shall provide funds solely for the planning or development of a program for a period of longer than two years.

(b) Each area health education center program must begin planning for at least one center during the first year of support so that at least one center is fully operational and meets all the applicable requirements of § 57.3805 during the third year of support. Additional centers may be phased in during the first four years of Federal support except that once planning for any center is initiated, it must become fully operational and meet all the applicable requirements of § 57.3805 within three years.

(c) Each school with which the Secretary enters into a contract under this subpart must meet all the requirements of § 57.3805 during the first four years of Federal support except that once planning to add any school is initiated it must meet all the applicable requirements of § 57.3805 within three years.

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[1] Entities that are receiving funds in fiscal year 1978 and 1979 to continue payments under contracts originally entered into under section 774 of the Act (as in effect on September 30, 1977) for projects for area health education center programs do not have to be conducted in accordance with these requirements, *except that* no payments can be made under these contracts in the fiscal year ending September 30, 1979, unless the entity provides assurances satisfactory to the Secretary that not later than September 30, 1979, the project for which payment is made will be a project described in section 781(a) of the Act and that the project will meet the requirements of section 781(b), (c) and (d) of the Act and applicable provisions of these regulations.

§ 57.3807 Evaluation of proposals.

The Secretary, after consultation with the National Advisory Council on Health Professions Education established by section 702 of the Act, shall find proposals technically acceptable or unacceptable after considering, among other pertinent factors:

(a) The potential effectiveness of the proposed project in carrying out the purposes of section 781 of the Act and this subpart;

(b) The degree to which the proposed project adequately provides for the program requirements set forth in § 57.3805;

(c) The capability of the offeror to carry out the proposed project; and

(d) The extent of the need of the area to be served by the proposed area health education center program.

§ 57.3808 Awards.

In determining which technically acceptable offerors will be awarded contracts, the Secretary will consider, among other factors, (a) the relative merit of the proposals, (b) the relative cost-efficiency of the proposals, and (c) any special factors relating to national needs as the Secretary may from time to time announce.

§ 57.3809 Restrictions on the amount and use of funds.

(a) The Secretary will not provide in any year under this subpart more than 75 percent of the total operating funds of an area health education center program.

(b) The area health education center program must spend at least 75 percent of the funds provided under this subpart in any year in area health education centers.

§ 57.3810 Applicability of procurement regulations.

Contracts made under this subpart shall be subject to all applicable provisions of the Federal Procurement Regulations, (41 CFR Chapter 1 *et seq.*) and Department of Health and Human Services Procurement Regulations (41 CFR Chapter 3).

§ 57.3811 Records and audits.

In addition to the record and audit requirements of the Federal and Department procurement regulations, the records and audit requirements of section 705 of the Act apply to contracts under this subpart.

PART 58—GRANTS FOR TRAINING OF PUBLIC HEALTH AND ALLIED HEALTH PERSONNEL

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Subpart A—Grants for Graduate Programs in Health Administration

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 791 of the Public Health Service Act, 90 Stat. 2303 (42 U.S.C. 295h).

SOURCE: 45 FR 51210, Aug. 1, 1980, unless otherwise noted.

§ 58.1 To what grant program do these regulations apply?

These regulations apply to the award of grants under section 791 of

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the Public Health Service Act to public or nonprofit private educational entities (including schools of social work and excluding schools of public health) to support graduate educational programs in health administration, hospital administration, and health planning.

§ 58.2 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended (42 U.S.C. 201 et. seq.).

"Council" means the National Advisory Council on Health Profession Education established by section 702 of the Act.

"Educational entity" means a school, college or university which is accredited by a body or bodies recognized for this purpose by the Secretary of Education.

"Graduate educational program" means a program of education leading to a master's degree or equivalent, or a doctoral degree or equivalent.

"Nonprofit," as applied to any entity, means an entity no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

"School of public health" means a school which provides training leading to a graduate degree in public health or an equivalent degree and which has been accredited by the Council on Education for Public Health as a school of public health.

"School year" means the traditional approximately 9-month September to June annual session at an educational institution.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department to whom the authority involved has been delegated.

"State" means any one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 58.3 Who is eligible to apply for a grant?

Any public or nonprofit educational entity (excluding schools of public health) located in a State is eligible to apply for a grant to support a graduate educational program which has been accredited for the training of individuals for health services administration, hospital administration, or health planning by a recognized body or bodies approved for this purpose by the Secretary of Education.

§ 58.4 What assurances must be provided in an application?

(a) The application must contain assurances satisfactory to the Secretary that:

(1) At least 25 individuals will complete the graduate educational programs of the applicant for which the application was made in the school year beginning in the fiscal year for which an applicant receives a grant;

(2) The applicant will expend or obligate at least $100,000 in funds from non-Federal sources to conduct the graduate educational program for which the application was made (excluding expenditures for construction, but not excluding expenditures for alterations and renovation) in the school year beginning in the fiscal year for which an applicant receives a grant;

(3) The applicant will maintain for the school year beginning in the fiscal year ending September 30, 1978, and for each subsequent school year for which a grant is applied for, a first year enrollment of full-time students in the graduate educational programs for which the application was made which exceeds the number of full-time first year students enrolled in that program in the school year beginning in the fiscal year ending September 30, 1976 by (i) 5 percent of that number if the number of full-time first-year students enrolled was 100 or less; or (ii) the greater of 2.5 percent of that number, or 5 students if the number of full-time first year students enrolled was more than 100. For purposes of this section the term "full-time student" means a student who is enrolled in an educational entity on a full-time basis as determined by the educational entity. The number of students enrolled in an educational entity for any year shall be the number en-

rolled as of October 15 of that school year. The classification of a full-time student as a first year student will be made in accordance with the usual policies of the educational entity, except that no student may be counted more than once as a first year student.

(b) The Secretary may, after consultation with the Council, waive in whole or in part the requirements of paragraph (a)(3) of this section relating to increases in enrollment upon written notification by the appropriate accreditation body or bodies that compliance with that paragraph will prevent the educational entity from meeting that body or bodies accrediting standards with respect to the graduate educational programs for which the application was made. In deciding whether to give a waiver under this paragraph the Secretary will consider the extent to which the educational entity has means available to it by which it could meet the increased enrollment requirements without failing to meet the accreditation standards.

§ 58.5 What activities must be addressed in an application?

Each application submitted under these regulations must include a plan, in the form the Secretary may prescribe, describing at least three of the following activities that will be undertaken to strengthen the applicant's graduate educational programs in health administration, hospital administration, or health planning:

(a) Providing training which will prepare health administrators and health planners for employment in a wide variety of settings, including public and voluntary agencies, extended care facilities, ambulatory facilities and health planning agencies;

(b) Developing or expanding special curriculum content in health planning, policy and regulation, health economics, quantitative methods and financial management;

(c) Providing field training in settings described in paragraph (a) of this section and which involves experience related to the curricular areas described in paragraph (b) of this section;

(d) Providing field training in settings designed to provide mid-career development for practicing health administrators and planners;

(e) Developing programs designed to provide regional educational opportunities in areas where there are no accredited programs in health services administration or in which there are documented shortages of trained health services administrators or planners.

§ 58.6 How is the amount of the grant award determined?

(a) The Secretary after consultation with the Council, will award grants annually to those educational entities which meet the requirements of section 791 of the Act, and of this subpart.

(b) The amount of each grant will be equal to the total amount of funds available for this purpose divided by the number of educational entities with approved applications.

§ 58.7 How long does grant support last?

(a) Each notice of grant award specifies the period during which funds from that annual award are available for obligation by the grantee. This period will not exceed two years. If at any time during the period of the grant it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, exceeds the grantee's needs for that period, the Secretary may adjust the amounts awarded by withdrawing the excess.

(b) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government to make any additional, supplemental, or other award with respect to any approved application or portion of an approved application.

§ 58.8 For what purposes may grant funds be spent?

(a) A grantee may spend grant funds it receives under this subpart for any purpose related to its graduate educational program in health administration, hospital administration, or health planning in accordance with the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

(c) Grant funds may not be expended for construction (except that grant funds may be used for alterations and renovation) or student assistance.

§ 58.9 What additional Department regulations apply to grantees?

Several other regulations apply to grantees. They include, but are not limited to:

42 CFR Part 50—PHS grant appeals process

45 CFR Part 16—Department grant appeals process

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates and other cost allocations)

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department—Implements Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs

45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in Federally assisted education programs

45 CFR Part 91[1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance.

§ 58.10 What other audit and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act concerning audit and inspection.

§ 58.11 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart B—Special Project Grants for Graduate Programs in Public Health

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 792 of the Public Health Service Act, 90 Stat. 2304 (42 U.S.C. 295h-1).

SOURCE: 45 FR 51557, Aug. 1, 1980, unless otherwise noted.

§ 58.20 To what program do these regulations apply?

These regulations apply to grants under section 792 of the Public Health Service Act to schools of public health and other educational institutions to support development of new graduate programs or the expansion of existing graduate programs in biostatistics or epidemiology; health administration, health planning, or health policy analysis and planning; environmental or occupational health; dietetics and nutrition, or maternal and child health.

§ 58.21 Definitions.

As used on this subpart:

"Act" means the Public Health Service Act, as amended (42 U.S.C. 201 et. seq.).

"Educational institution" means a school, college, or university which offers or proposes to offer a graduate program to prepare public and community health personnel.

"Graduate program" means a program of education leading to a master's degree or equivalent, or a doctoral degree or equivalent, or a postbaccalaureate educational program for practicing public and community health personnel as defined in section 793(d) of the Act (42 U.S.C. 295h-2).

"Nonprofit", as applied to any entity, means an entity no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

"School of public health" means a school which provides training leading to a graduate degree in public health or an equivalent degree and which has been accredited by the Council on Education in Public Health as a school of public health.

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[1] When issued.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department to whom the authority involved has been delegated.

"State" means any one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 58.22 Who is eligible to apply for a grant?

(a) Section 792(a) of the Public Health Service Act, as amended, authorizes the Secretary to make grants to accredited schools of public health to develop new programs or to expand existing graduate programs in:

(1) Biostatistics or epidemiology,

(2) Health administration, health planning, or health policy analysis and planning,

(3) Environmental or occupational health,

(4) Dietetics and nutrition, or

(5) Maternal and child health.

(b) Section 792(b) of the Public Health Service Act, as amended, authorizes the Secretary to award grants to assist in other public or nonprofit private educational entities meeting the costs of special projects in:

(1) Biostatistics or epidemiology,

(2) Health administration, health planning, or health policy analysis and planning,

(3) Environmental or occupational health, or

(4) Dietetics and nutrition.

§ 58.23 Project requirements.

(a) A graduate program in *dietetics and nutrition* must prepare individuals, upon completion of the graduate program, for leadership roles in community nutrition, including the application of specialized knowledge to problems in community nutrition. It does not include basic professional training required for entry level employment as a registered dietitian nor technical training in clinical dietetics.

(b) A graduate program in *environmental or occupational health* must provide training to prepare individuals upon completion of the graduate program for policy development roles in the definition and solution of environmental or occupational health problems and the management of environmental systems in which humans live and work. Although it does not include technical training of industrial hygienists it does include training of technologists at the graduate level.

(c) A graduate program in *biostatistics* must prepare individuals, upon completion of the graduate program, in the application of statistical principles, techniques and methods to the identification and solution of health problems and the provision of health services and does not include preparation of individuals in research biostatistics (e.g., pharmaceutical areas (drugs, medication, dosage determination)).

(d) A graduate program in *epidemiology* must prepare individuals upon completion of the graduate program, in the knowledge and skills necessary to the identification of factors which influence or determine the occurrence of community health problems, the methods essential for their solution, and patterns for the provisions of health services.

(e) A graduate program in *health administration, health planning, or health policy analysis and planning* must prepare individuals, upon completion of the graduate program, in the organization, policy formulation, planning, evaluation and management of health services systems in accordance with § 58.24(f).

(f) A graduate program in *maternal and child health* must qualify the graduate for leadership and policy development roles in the administration of maternal and child health programs and the application of public health methods for the reduction of the incidence and prevalence of problems of pregnancy, parturition, motherhood, infancy, and childhood.

§ 58.24 How will applications be evaluated?

The Secretary will decide which applications to approve by considering among other factors:

(a) The potential of each project to meet its stated objectives;

(b) The administrative and managerial capability of each applicant to carry out its project;

(c) The soundness of the applicant's fiscal plan for assuring effective utilization of grant funds;

(d) The adequacy of the staff and faculty to carry out the training program;

(e) The potential of the training program to be implemented and continued on a self-sustaining basis; and

(f) With respect to applications for graduate programs in health administration, health planning, or health policy analysis and planning, whether each project includes:

(1) Graduate programs with broadly based training for health services administrators and planners as preparation for employment in a wide variety of health related organizations including public and voluntary agencies, extended care facilities, ambulatory care facilities, and health systems or planning agencies.

(2) Development or expansion of curriculum in health planning, policy and regulation, health economics, and quantitative methods or financial management in graduate programs in health administration.

(3) Graduate programs with field training in settings listed in paragraph (f)(1) of this section which involve experiences related to health planning, health economics, quantitative methods or financial management.

(4) Development or expansion of intensive short courses or external courses to enhance the competencies of practicing health services administrators and planners in the areas of health policy, health planning and regulation, health economics, quantitative methods and financial management.

(5) Graduate programs designed to meet needs for health services administration and planning personnel in geographic regions which have documented shortages of such personnel.

The Secretary will award grants within the limits of funds available to those approved applicants whose projects will best promote, in his or her judgment, the purposes of section 792 of the Act.

§ 58.25 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed three years.

(b) Generally, the grant will initially be funded for one year, and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of factors such as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

(d) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for that period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

(e) If a grantee wishes to continue the grant beyond the project period originally approved, a renewal application must be submitted. This application will be treated as a competitive application. However, the maximum length of support for any particular project (including renewals) may not exceed five years.

§ 58.26 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or any religious purpose.

§ 58.27 What additional Department regulations apply to grantees?

Several other regulations apply to these grants. They include, but are not limited to:

42 CFR Part 50—PHS grant appeals process

45 CFR Part 16—Department grant appeals process

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates and other cost allocations)

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance from the Department—Implements Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80

45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs

45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally assisted programs

45 CFR Part 86—Nondiscrimination on the basis of sex in Federally assisted education programs

45 CFR Part 91 [1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance—

§ 58.28 What other recordkeeping audit and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act concerning audit and inspection.

§ 58.29 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart C—Grants for Public Health Traineeships for Students in Schools of Public Health and in Other Graduate Public Health Programs

Authority: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 748 of the Public Health Service Act, 90 Stat. 2279, as amended by 91 Stat. 1505 (42 U.S.C. 294r).

Source: 45 FR 73661, Nov. 6, 1980, unless otherwise noted.

§ 58.201 To what grant program do these regulations apply?

These regulations apply to the award of grants to eligible educational entities under section 748 of the Public Health Service Act (42 U.S.C. 294e) to provide funds for traineeships for students enrolled in graduate or specialized training in public health.

§ 58.202 Definitions.

"Act" means the Public Health Service Act, as amended.

"Educational entity" means a school, college, or university which is accredited by a body or bodies recognized for this purpose by the Secretary of Education or an institution which provides specialized training in public health or specialized training in preventive medicine or dentistry.

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[1] When used.

"Fiscal year" means the Federal fiscal year, beginning October 1 and ending the following September 30.

"Full-time student" means a student who is either (1) in a residency program in preventive medicine or dentistry or (2) is enrolled on a full-time basis in a graduate program in public health and who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters of other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

"Graduate program" or "graduate training" means a program of education leading to a master's degree or equivalent or doctoral degree or equivalent.

"National of the United States" means (as defined in the Immigration and Nationality Act at 8 U.S.C. 1101(a)(22)) (1) a citizen of the United States or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States.

"Nonprofit," as applied to any entity, means one in which no part of the net earnings inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"Secretary" means the Secretary of the Department of Health and Human Services or any officer or employee of the Department to whom the authority involved has been delegated.

"School of public health" means a school which provides training leading to a graduate degree in public health or equivalent degree and which has been accredited by the Council on Education for Public Health as a school of public health.

"Specialized training in public health" or "specialized training in preventive medicine or denistry" means a residency training program approved by the Liaison Committee on Graduate Medical Education or by the Commission on Dental Accreditation leading to board eligibility in a specialty in preventive medicine or dental public health respectively.

"State" means any one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

"Trainee" means a student who is receiving traineeship funds from a grant made under these regulations.

§ 58.203 Who is eligible to apply for a grant?

The following are eligible for grants:

(a) Any accredited school of public health which is located in a State; and

(b) Any other public or nonprofit private eduational entity which is located in a State and provides graduate or specialized training in public health. However, no entity of this type may obtain an award under this subpart to support traineeships in health administration, hospital administration, or health policy analysis and planning.[1]

§ 58.204 How will applications be evaluated?

(a) The Secretary will award a grant to each eligible school of public health which submits an application containing all the information and assurances requested in the required form and time.

(b) For public and nonprofit educational entities other than schools of public health, the Secretary will decide which applications to approve by considering, among other factors:

(1) The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner;

(2) The degree of need for the professionals to be trained; and

(3) The adequacy of the staff and faculty; and

(4) Whether the applicant's graduate programs in environmental or occupational health or dietetics and nutrition, or both, meet the require-

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[1] For traineeships in health administration, hospital administration, or health policy analysis and planning, eduational entities which are *not* accredited schools of public health may only apply under Section 749 of the Act.

ments in paragraphs § 58.208(c) and (d).

Within the limits of funds available for competing awards the Secretary will award grants to those approved applicants whose traineeship programs will best promote the purposes of section 748 of the Act.

§ 58.205 How is the amount of the award determined?

(a) *Grants to schools of public health.* (1) Each year, the Secretary will designate a percentage of the traineeship funds appropriated to implement section 748 of the Act for awards to schools of public health, and will announce the amount of funds to be allocated in the FEDERAL REGISTER, as soon as possible after making the designation.

(2) The Secretary will use a formula to determine the amount of the grant to be awarded to each school of public health with an approved application. This formula is

$$G = \frac{SS}{TS} \times AF.$$

G is the amount of the grant award; SS is the number of students enrolled in graduate and specialized training in public health at the school; TS is the total number of students enrolled in graduate and specialized training in all schools of public health with approved applications; and AF is the amount of traineeship funds under this program that the Secretary has designated for award to schools of public health for that fiscal year. The Secretary will determine the number of students enrolled in graduate and specialized training in public health at the school (SS) with the formula

$$SS = FTS + \frac{PTC}{9}$$

FTS is the number of full-time students, and PTC is the total number of credit hours in which part-time students are enrolled. If necessary, the figure for

$$\frac{PTC}{9}$$

will be rounded to the next highest number. Students will be counted as of October 15 of the fiscal year in which application is made. The amount of a grant will never exceed the amount requested by the applicant.

(b) *Grants to public and nonprofit private educational entities.* The remaining funds will be available to meet continuation commitments and to award on a competitive basis to eligible public or nonprofit private educational entities other than schools of public health. The Secretary will determine the amount of these awards by estimating the sum necessary during the budget period to cover the tuition, fees, stipends, and allowances (including travel costs approved by the Secretary) for full-time students, and the tuition and fees for part-time students which the applicant proposes to provide to its trainees.

§ 58.206 How long does grant support last?

(a) The written notice of grant award specifies the period during which formula grant funds are available for obligation by the grantee, or the period during which the recipient of a competitive grant award need not recompete for funds. This period will not exceed one year for formula grants and 3 years for competitve grants. The period during which recompetition is not necessary is called the project period.

(b) Generally a competitive grant will initially be funded for one year, and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

(d) Any balance of Federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withholding the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 58.207 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations. Use of grant funds to meet the direct or indirect administrative costs of the training institution is not authorized.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

§ 58.208 What are the requirements for traineeships and the appointment of trainees?

(a) Schools of Public Health must award at least 45 percent of the grant funds received for the fiscal year ending September 30, 1978, at least 55 percent of the grant funds received in the fiscal year ending September 30, 1979, and at least 65 percent of the grant funds received in the fiscal year ending September 30, 1980, and in succeeding fiscal years, to individuals who:

(1) Have previously received a postbaccalaureate degree, or have 3 years of work experience in health services, and

(2) Are pursuing graduate training in (i) biostatistics or epidemiology, (ii) health administration, health planning, or health policy analysis and planning, (iii) environmental or occupational health, (iv) dietetics or nutrition, (v) maternal and child health, or (vi) are pursuing specialized training in preventive medicine or dentistry.

(b) Public or nonprofit private educational entities other than schools of public health must award at least 45 percent of the grant funds received for the fiscal year ending September 30, 1978, at least 55 percent of the grant funds received for the fiscal year ending September 30, 1979, and at least 65 percent of the grant funds received in the fiscal year ending September 30, 1980, and in succeeding fiscal years, to individuals who:

(1) Have previously received a postbaccalaureate degree, or have 3 years of work experience in health services, and

(2) Are pursuing graduate training in (i) biostatistics or epidemiology, (ii) environmental or occupational health, (iii) dietetics or nutrition, (iv) maternal and child health; or (v) are pursuing specialized training in preventive medicine or dentistry.

(c) Graduate training in environmental or occupational health must provide training to prepare individuals for policy development roles in the definition and solution of environmental or occupational health problems and the management of environmental systems in which humans live and work. Although it does not include the technical training of industrial hygienists, it does include training of environmental health technologists at the graduate level.

(d) Graduate training in dietetics and nutrition must provide training as preparation for leadership roles in community nutrition, and must include training in human nutritional requirements and in the application of specialized knowledge to the analysis and solution of community or population group nutritional problems. Graduate training in dietetics may not provide basic professional training required for entry level employment as a registered dietitian nor technical training in clinical dietetics.

(e) Graduate training programs may not include more than four months of field training unless expressly approved by the Secretary.

(f) The grantee must require each trainee to complete a statement of appointment by the beginning of the training period, or as soon as possible if the trainee receives notice of his or her traineeship appointment after the training period has begun. The program director must sign the statement on behalf of the grantee and the original copy of the statement must be retained by the grantee to be available for program review and financial audit. The grantee must also send a copy of the statement to the Secretary upon request.

(g) The grantee must require full-time trainees to sign a statement that they will not undertake employment during their traineeships which would interfere with their ability to satisfactorily complete the training program in a timely fashion.

(h) The grantee may not require trainees to perform any work which is not an integral part of their training program and required of all students in the program, or to perform services which detract from or prolong their training.

(i) The grantee must advise each trainee who is enrolled in a course of study which requires more than twelve months that continued support under this program is contingent upon the continued availability of grant funds.

§ 58.209 Who is eligible for financial assistance as a trainee?

To be eligible for a traineeship, an individual must meet the following conditions:

(a) The individual must be a national of the United States, a lawful permanent resident of the United States, Puerto Rico, the Virgin Islands, or Guam; or a permanent resident of the Trust Territory of the Pacific Islands or the Northern Mariana Islands.

(b) The individual may not be receiving concurrent support for the same training from another Federal source except education benefits under the Veterans Readjustment Benefits Act;

(c) The individual must be accepted for enrollment, or be enrolled in graduate training at a school of Public Health in (1) biostatistics or epidemiology, (2) health administration, health planning, or health policy analysis and planning, (3) environmental or occupational health, (4) dietetics or nutrition, (5) maternal and child health, (6) other graduate training in public health; or specialized training in preventive medicine or dentistry; or

(d) Be accepted for enrollment, or be enrolled in graduate training at another public or nonprofit private educational entity in (1) biostatistics or epidemiology, (2) environmental or occupational health, (3) dietetics or nutrition, (4) maternal and child health, (5) other graduate training in public health (excluding graduate training in health administration, health planning, or health policy analysis and planning), or specialized training in preventive medicine or dentistry.

§ 58.210 What financial support is available to trainees?

(a) Expenditures are limited to:

(1) Tuition and fees, in accordance with the established rates of the institution except as limited by the Secretary.

(2) Stipends, for full time students, in whatever amount the grantee determines that each trainee needs to pursue the training program, as long as that amount does not exceed the limits established by the Secretary.

(3) Transportation allowances on an individual basis when prior approval has been obtained from the Secretary in the following circumstances:

(i) In cases of extreme need, the grantee may pay a trainee an allowance from grant funds for travel from his or her residence to the training site.

(ii) The grantee may pay a trainee an allowance from grant funds for travel to field training if the site is beyond a reasonable commuting distance and requires the trainee to establish a temporary new residence. However, the grantee may not pay an allowance for daily commuting from the new place of residence to the field training headquarters.

(iii) The grantee may pay a trainee an allowance from grant funds for domestic travel to conduct research to meet dissertation requirements.

(b) The grantee may not give a stipend or allowance to a part-time trainee, but may give a traineeship award to pay a part-time trainee's tuition and fees.

§ 58.211 Duration of traineeships.

Traineeships must be for a full academic year, except an appointment for less than a full academic year may be made when the student will complete the program of study at the termination of the appointment, or when joint-degree programs require enrollment at another unit of the grantee institution for part of the academic year. A traineeship may not exceed 12 months in duration. However, consecutive or subsequent traineeship appointments may be made if a student's required program of study exceeds 12 months. Training for which the student receives a traineeship must begin during the period for which funds are made available, but may extend beyond the end of this period.

§ 58.212 Termination of traineeship.

The grantee must terminate a traineeship:

(a) Upon request of the trainee;

(b) If the trainee withdraws from the grantee institution; or

(c) If the grantee determines that

(1) The trainee is no longer an enrolled student; or

(2) The trainee is not eligible or able to continue in attendance in accordance with its standards and practices.

§ 58.213 What additional Department regulations apply to grantees?

Several other regulations apply to grantees. They include, but are not limited to:

42 CFR Part 50—PHS grant appeals process.
45 CFR Part 16—Department grant appeals process.
45 CFR Part 46—Protection of human subjects.
45 CFR Part 74—Administration of grants.
45 CFR Part 80—Nondiscrimination under programs receiving Federal Assistance—Implements Title VI of the Civil Rights Act of 1964.
45 CFR Part 81—Practice and procedure for hearings under Part 80.
45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs.
45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally assisted programs.
45 CFR Part 86—Nondiscrimination on the basis of sex in Federally assisted education programs.
45 CFR Part 91[1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance.

§ 58.214 What other audit and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act concerning audit and inspection.

§ 58.215 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart D—Grants for Traineeships in Health Administration, Hospital Administration, or Health Policy Analysis and Planning at Public or Nonprofit Private Educational Institutions Other than Schools of Public Health

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 749 of the Public Health Service Act, 90 Stat. 2280 (42 U.S.C. 294s).

SOURCE: 45 FR 73658, Nov. 6, 1980, unless otherwise noted.

§ 58.221 To what grant program do these regulations apply?

These regulations apply to the award of grants to eligible educational entities under section 749 of the Public Health Service Act to provide funds for traineeships for students enrolled in graduate programs in health administration, hospital administration, or health policy analysis and planning.

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[1] When issued.

§ 58.222 Definitions.

"Act" means the Public Health Service Act, as amended.

"Educational entity" means a school, college, or university which is accredited by a body or bodies recognized for this purpose by the Secretary of Education.

"Fiscal year" means the Federal fiscal year, beginning October 1 and ending the following September 30.

"Full-time student" means a student who is enrolled on a full-time basis in a graduate program in health administration, hospital administration, or health policy analysis and planning, and who is enrolled for a sufficient number of credit hours in any semester or other academic term to enable him or her to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study at the school in which the student is enrolled.

"Graduate program" means a program of education leading to a master's degree or equivalent or a doctoral degree or equivalent.

"National of the United States" (as defined in 8 U.S.C. 110(a)(22), the Immigration and Nationality Act) means: (1) A citizen of the United States or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States.

"Nonprofit," as applied to any entity, means one which is a corporation or association, or is owned or operated by one or more corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"Secretary" means the Secretary of the Department of Health and Human Services or any officer or employee of the Department to whom the authority involved has been delegated.

"School of public health" means a school which provides training leading to a graduate degree in public health or equivalent degree and which has been accredited by the Council on Education for Public Health as a school of public health.

"State" means any one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

"Trainee" means a student who is receiving traineeship funds from a grant made under these regulations.

§ 58.223 Who is eligible to apply for a grant?

Any public or nonprofit private educational entity (excluding schools of public health), located in a State, is eligible to apply for a grant to support traineeships in its graduate program in health administration, hospital administration, or health policy analysis and planning which has been accredited by a body or bodies approved for this purpose by the Secretary of Education.

§ 58.224 How will applications be evaluated?

The Secretary will award a grant to each eligible entity which submits all the information and assurances requested in the required form and time.

§ 58.225 How is the amount of the award determined?

The Secretary will use a formula to determine the amount of the grant award for each entity with an approved application. This formula is:

$$G = \frac{SS}{TS} \times AF$$

G is the amount of the grant award; SS is the number of students enrolled in approved graduate programs in health administration, hospital administration, or health policy analysis and planning at the school; TS is the total number of students in these programs at all schools with approved applications, and AF is the amount of available funds authorized under section 749 for traineeships in a given fiscal year. The Secretary will determine the number of students enrolled in these programs at the school (SS) with the formula:

$$SS = FTS + \frac{PTC}{9}$$

FTS is the number of full-time students enrolled in these programs and PTC is the total number of credit hours in which part-time students are enrolled. If necessary, the figure for PTC/9 will be rounded to the next highest number. Students will be counted as of October 15 of the fiscal year in which application is made. The amount of a grant will never exceed the amount requested by the applicant.

§ 58.226 How long does grant support last?

(a) The notice of grant award specifies the period during which funds are available for obligation by the grantee. This period will not exceed one year. If at any time during the period of the grant it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, exceeds the grantee's needs for that period, the Secretary may adjust the amounts awarded by withdrawing the excess.

(b) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

§ 58.227 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles in Subpart Q of 45 CFR Part 74, and these regulations. Use of traineeship funds to meet the direct or indirect administrative costs of the training institution is not authorized.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

§ 58.228 What are the requirements for traineeships and the appointment of trainees?

(a) The grantee must award at least 80 percent of its grant funds to individuals who have previously received a postbaccalauteate degree or have three years work experience in health services.

(b) Graduate training programs may not include more than four months of field training unless expressly approved by the Sectretary.

(c) The grantee must require each trainee to complete a statement of appointment by the beginning of the training period, or as soon as possible if the trainee receives notice of his or her traineeship appointment after the training period has begun. The program director must sign the statement on behalf of the grantee and the original copy of the statement must be retained by the grantee to be available for program review and financial audit. The grantee must also send a copy of the statement to the Secretary upon request.

(d) The grantee must require full-time trainees to sign a statement that they will not undertake employment during their traineeships which would interfere with their ability to satisfactorily complete the training program in a timely fashion.

(e) The grantee may not require trainees to perform any work which is not an integral part of their training program and required of all students in the program, or to perform services which detract from or prolong their training.

(f) The grantee must advise each trainee who is enrolled in a course or study which requires more than twelve months to complete that continued support from funds awarded under this program is contingent upon the continued availability of grant funds.

§ 58.229 Who is eligible for financial assistance as a trainee?

To be eligible for a traineeship, an individual must meet the following conditions:

(a) The individual must be a national of the United States, a lawful permanent resident of the United States, Puerto Rico, the Virgin Islands, or Guam, or a permanent resident of the Trust Territory of the Pacific Islands or the Northern Mariana Islands.

(b) The individual must be accepted for enrollment, or be enrolled in a grantee's accredited graduate program in health administration, hospital administration, or health policy analysis and planning;

(c) The individual may not be receiving concurrent support for the same training from another Federal source except education benefits under the Veteran's Readjustment Benefits Act.

§ 58.230 What financial support is available to trainees?

(a) The grantee may use grant funds to pay for:

(1) Tuition and fees, in accordance with the established rates of the institution except as limited by the Secretary;

(2) Stipends, for full time trainees in whatever amount the grantee determines that each trainee needs to pursue the training program, as long as that amount does not exceed the limits established by the Secretary;

(3) Transportation allowances on an individual basis when prior approval has been obtained from the Secretary in the following circumstances:

(i) In cases of extreme need, the grantee may pay a trainee an allowance from grant funds for travel from his or her residence to the training site.

(ii) The grantee may pay a trainee an allowance from grant funds for travel to field training if the site is beyond a reasonable commuting distance and requires the trainee to establish a temporary new residence. However, the grantee may not pay an allowance for daily commuting from the new place of residence to the field training headquarters.

(iii) The grantee may pay a trainee an allowance from grant funds for domestic travel to conduct research to meet dissertation requirements.

(b) The grantee may not give a stipend or allowance to a part-time trainee, but may give a traineeship award to pay a part-time trainee's tuition and fees.

§ 58.231 Duration of traineeships.

A traineeship must be for a full academic year except that an appointment for less than a full academic year may be made to a student who will complete his or her program of study in a lesser time or when joint-degree programs require enrollment at another unit of the grantee institution for part of the academic year. A traineeship may not exceed 12 months in duration. However a grantee may make consecutive or subsequent traineeship appointments to students whose required program of study exceeds 12 months. The training for which a student receives a traineeship must begin during the period for which funds are made available, but may extend beyond that period.

§ 58.232 Termination of traineeships.

The grantee must terminate a traineeship:

(a) Upon request of the trainee;

(b) If the trainee withdraws from the grantee institution; or

(c) If the grantee determines that:

(1) The trainee is no longer an enrolled student; or

(2) The trainee is not eligible or able to continue in attendance in accordance with its standards and practices.

§ 58.233 What additional Department regulations apply to grantees?

Several other Department regulations apply to grantees. They include, but are not limited to:

42 CFR Part 50—PHS grant appeals process.
45 CFR Part 16—Department grant appeals process.
45 CFR Part 46—Protection of human subjects.
45 CFR Part 74—Administration of grants.
45 CFR Part 80—Nondiscrimination under programs receiving Federal Assistance—Implements Title VI of the Civil Rights Act of 1964.
45 CFR Part 81—Practice and procedure for hearings under Part 80.

45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs.

45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally assisted programs.

45 CFR Part 86—Nondiscrimination on the basis of sex in Federally assisted education programs.

45 CFR Part 91[1]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance.

§ 58.234 What other audit and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act, concerning audit and inspection.

§ 58.235 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart E—Grants for Allied Health Projects

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 796, Public Health Service Act, 90 Stat. 2307 (42 U.S.C. 295h-5).

SOURCE: 45 FR 48624, July 21, 1980, unless otherwise noted.

§ 58.401 To what programs do these regulations apply?

These regulations apply to grants under section 796 of the Public Health Service Act (42 U.S.C. Part 295h-5) for planning, developing, demonstrating, operating, and evaluating projects to:

(a) Establish regional or State systems to assure that allied health and nursing personnel needs in the area are met by coordinating and managing allied health professions and nursing education and training within and among educational institutions and their clinical affiliates;

(b) Establish or improve recruitment, training, and retraining programs for allied health personnel; and

(c) Establish career ladders and advancement programs for practicing allied health personnel.[1]

§ 58.402 Definitions.

"Act" means the Public Health Service Act.

"Allied health personnel" means individuals with at least one academic year of substantive health training beyond the high school level, including clinical training, in a field which qualifies them to: (a) Support, complement, or supplement physicians, dentists, and other health professionals in the delivery of health care of patients, or (b) assist environmental engineers in environmental health control and preventive medicine activities.

"College or university" means a public or nonprofit private educational institution which is accredited by a recognized body or bodies approved for this purpose by the Secretary of Education.

"Junior college" means a public or nonprofit private school accredited by a recognized body or bodies approved for this purpose, which provides education programs beyond the high school level and offers an associate degree as the highest earned academic degree.

"Nonprofit," as applied to an entity, means an entity no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"Secretary" means the Secretary of the Department of Health and Human Services or any officer or employee of the Department to whom the authority involved has been delegated.

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[1] When issued.

[1] The following additional purposes provided for under section 796 of the Act will be supported by contract:

(1) The establishment of new roles and functions for allied health personnel and methods for increasing the efficiency of health manpower through more effective use of allied health personnel in various practice settings;

(2) The establishment of new or improved methods of credentialing allied health personnel; and,

(3) The establishment of continuing education programs for practicing allied health personnel.

"State" includes, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

"Training Center for allied health professions" or "center" means a junior college, college, or university which:

(a) Provides educational programs leading to an associate, baccalaureate, or higher degree in any of the following disciplines:

Doctoral Degree

Clinical Psychologists

Master's Degree

Speech Pathology/Audiology

Bachelor's Degree

Dietitian (Coordinated undergraduate program)
Community Health Educator
Health Services Administrator
Medical Record Administrator
Medical Technologist
Occupational Therapist
Physical Therapist
Primary Care Physician Assistant
Sanitarian (Environmental Health)

Associate Degree

Clinical Dietetic Technician
Cytotechnologist
Dental Assistant
Dental Hygienist
Dental Laboratory Technician
Medical Assistant
Medical Laboratory Technician
Medical Record Technician
Occupational Therapy Assistant
Ophthalmic Medical Assistant
Optometric Technician
Physical Therapy Assistant
Radiologic Technologist
Respiratory Therapist
Sanitarian Technician

(b) Provides training for no fewer than 20 persons in the substantive health portion, including clinical experience as required for employment, in three or more of the disciplines listed in paragraph (a) of this definition, and has a minimum of six full-time students in that portion of each curriculum by October 15 of the fiscal year of application;

(c) Has a teaching hospital as part of the grantee institution or is affiliated with a teaching hospital my means of a written agreement meeting the requirements of § 58.404. The term "teaching hospital" includes other settings which provide clinical or other health services if they fulfill the requirement for clinical experience specified in an allied health curriculum;

(d) Is accredited institutionally and programmatically (if programmatic accreditation is required for graduates to be licensed or certified) by a recognized body or bodies approved for this purpose by the Secretary of Education or provides assurance satisfactory to the Secretary from the appropriate accrediting body that reasonable progress is being made toward accreditation; and

(e) Has a single administrative unit with an identified budget and faculty which is responsible for:

(1) All allied health education programs offered by the center;

(2) Allied health curriculum development;

(3) Allied health student recruitment and counseling;

(4) Development of appropriate clinical affiliations;

(5) Placement of students for the clinical portion of the program; and

(6) Standards of student performance in technical portions of the program.

§ 58.403 Who is eligible to apply for a grant?

The following entities are eligible to apply for a grant under this subpart:

(a) States, political subdivisions of States, or regional and other public bodies representing States or political subdivisions of States or both,

(b) Colleges or universities or junior colleges located in a State, or State higher educational system, including but not limited to those with a training center for allied health professions (as defined in § 58.402). If the project for which support is requested includes clinical training, these entities must have an affiliation, as described in § 58.404, with a clinical facility,

(c) Public or nonprofit private entities located in a State, which provide

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health services and have an affiliation, as described in § 58.404, with a junior college, college, or university, or

(d) Other public or nonprofit private entities capable, as determined by the Secretary, of carrying out projects described in § 58.406.

§ 58.404 What are the requirements of an affiliation?

The affiliations required of centers in § 58.402 and of public or nonprofit private entities in § 58.403(b) and (c) must be evidenced by written agreements which include the following:

(a) A description of the working relationship and the responsibilities of the junior college, college, or university, and the entity providing health services, and of their joint responsibility with respect to the clinical and academic training of the program;

(b) An assurance that the curriculum and resources of the program have been examined and approved by both the faculty of the junior college, college, or university, and by the staff of the entity providing health services;

(c) A description of the method of enforcement of the agreement; and

(d) A description of the procedure for termination of the agreement.

§ 58.405 [Reserved]

§ 58.406 What projects can be supported?

(a) The following projects are eligible for grants under this subpart:

(1) Projects to plan, develop, demonstrate, operate, and evaluate a regional or State system to coordinate and manage allied health and nursing education and training within and among educational institutions and their clinical affiliates which perform all of the following activities:

(i) Assemble, analyze, and distribute data on allied health and nurse manpower supply and needs for the region or State which the project serves;

(ii) Maintain and distribute data on operating allied health and nursing education programs within the region or State which the project serves;

(iii) Coordinate experimental activities within the region or State being served which affect the education or training of allied health professionals and nurses; and

(iv) Develop rationales for establishing new or continuing existing educational programs for allied health and nursing personnel, determining required enrollment levels, and assuring adequate clinical affiliations for these programs.

(2) Projects to plan, develop, demonstrate, operate, and evaluate programs to establish or improve the recruitment, training, and retraining of allied health personnel, which include at least one of the following activities:

(i) Improving the quality of the allied health curricula by:

(A) Relating course content, methods, and progress evaluation to necessary job skills;

(B) Integrating didactic and clinical education to streamline and improve the entire learning experience; and

(C) Using and developing more creative and effective teaching or student progress evaluation procedures in didactic or clinical education;

(ii) Improving coordination between programs for the education or training of allied health personnel, both within institutions and among cooperating institutions;

(iii) Implementing training programs for specific groups, such as returning veterans, disadvantaged persons, minorities, the handicapped, persons with limited English speaking ability, and persons re-entering an allied health field;

(iv) Expanding enrollment in allied health training programs in fields in which there is a documented need for allied health personnel; or

(v) Establishing allied health training programs in the area served by the institution if there is a documented need for the program or a documented allied health manpower shortage.

(3) Projects to plan, develop, demonstrate, operate, and evaluate programs to establish career ladders or improved programs for practicing allied health personnel which:

(i) Establish a system for career advancement for allied health personnel at the place of employment, such as structured work experiences to enable them to advance their job levels and responsibilities within their fields, or

(ii) Provide college education, on a full or part-time basis, for presently employed allied health personnel which will enable them to advance within their fields.

(b) The following projects are ineligible for funding under this subpart:

(1) Projects which provide inservice training, which is training offered by an entity principally for the employees of that entity, and

(2) Projects which provide continuing education, which is training needed by persons currently employed in a field of allied health to maintain competency at the current entry level.

§ 58.407 Project requirements.

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) Each program must have a program director who is responsible for the conduct of the program and has been approved by the Secretary.

(b) In the case of projects described in § 58.406(a)(2) and (3), the grantee must complete the following program development activities within one year:

(1) The selection and appointment of key staff;

(2) The development of the curriculum and courses, where applicable; and

(3) Acquisition of additional staff and other resources necessary to implement the program.

§ 58.408 How will applications be evaluated?

The Secretary will decide which applications to approve by considering among other factors:

(a) The potential effectiveness of the proposed project in carrying out the purposes of section 796 of the Act;

(b) The degree to which the proposed project adequately provides for the project requirements set forth in § 58.407;

(c) The administrative and management ability of the applicant to carry out the proposed project in a cost effective manner;

(d) The potential of the project to continue on a self-sustaining basis after the period of grant support; and

(e) The adequacy of the staff and faculty.

The Secretary will award grants within the limits of funds available to those approved applicants whose projects will best promote the purposes of section 796 of the Act. At least fifty percent of the funds appropriated for these grants will be reserved for award to training centers for allied health professions, as defined in § 58.402.

§ 58.409 How long does grant support last?

(a) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed three years. The total length of support, including renewal, may not exceed five years.

(b) Generally, the grant will initially be funded for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of factors such as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

(d) Any balance of Federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withholding the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 58.410 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

§ 58.411 What health planning requirements must be met?

A grant may be made under this subpart only if the applicable requirements of Title XV of the Act relating to review and approval by the appropriate health systems agency have been met.

§ 58.412 What additional Department regulations apply to grantees?

Several other regulations apply to these grants. They include, but are not limited to:

42 CFR Part 50—PHS grant appeals process
45 CFR Part 16—Department grant appeals process
45 CFR Part 74—Administration of grants
45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department—Implements Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and procedure for hearings under Part 80
45 CFR Part 83—Nondiscrimination on the basis of sex in the admission of individuals to training programs
45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally assisted programs
45 CFR Part 86—Nondiscrimination on the basis of sex in Federally assisted education programs
45 CFR Part 91[2]—Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance.

§ 58.413 What other recordkeeping, audit and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act concerning recordkeeping, audit, and inspection.

§ 58.414 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of any award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart F—Grants for Traineeships for the Advanced Training of Allied Health Personnel

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 787 of the Public Health Service Act, 90 Stat. 2308 (42 U.S.C. 295h-6).

SOURCE: 45 FR 73665, Nov. 6, 1980, unless otherwise noted.

§ 58.501 To what programs do these regulations apply?

These regulations apply to grants to colleges, universities, and other public or private nonprofit entities under section 797 of the Public Health Service Act (42 U.S.C. 295h-6) to provide funds for traineeships for the advanced training of allied health personnel to:

(a) Teach in allied health training programs, or

(b) Serve in administrative or supervisory capacities.

§ 58.502 Definitions.

"Act" means the Public Health Service Act.

"Allied Health Advanced Traineeship program" means a program of advanced training of at least one academic year in length providing a master's or other higher degree which qualifies the trainee to serve as a teacher, administrator, or supervisor in allied health fields.

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[2] When issued.

"Allied health personnel" means individuals with at least one academic year of post-secondary training, including clinical training, in a field which qualifies them to:

(a) Support, complement, or supplement physicians, dentists, and other health professionals in the delivery of health care to patients, or

(b) Assist environmental engineers in environmental health control and preventive medicine activities.

"Allied Health Training Institute program" means a program of advanced training, to improve the capability of allied health personnel to serve in teaching, administrative, or supervisory capacities, which is at least two and one-half days but less than one academic year in length.

"College or university" means a public or private nonprofit educational institution which is accredited by a recognized body or bodies approved for this purpose by the Secretary of Education.

"National of the United States" means: (1) A citizen of the United States or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States (as defined in 8 U.S.C. 1101(a)(22), the Immigration and Nationality Act).

"Nonprofit private entity" means an entity no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

"Secretary" means the Secretary of the Department of Health and Human Services or any officer or employee of the Department to whom the authority involved has been delegated.

"State" means any one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

"Trainee" means a student who is receiving a traineeship from a grant under these regulations.

§ 58.503 Who is eligible to apply for a grant?

(a) *Allied Health Advanced Traineeship.* Any accredited college or university is eligible to apply if it is located in a State and provides or is able to provide a graduate level Allied Health Advanced Training program.

(b) *Allied Health Training Institute.* Any public or nonprofit private entity is eligible to apply for a grant if it is located in a State and provides or is able to provide an Allied Health Training Institute program.

§ 58.504 [Reserved]

§ 58.505 How will applications be evaluated?

The Secretary will decide which applications to approve by considering, among other factors:

(a) The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner;

(b) The relative need for the program; and

(c) The adequacy of the staff and faculty.

The Secretary will award grants within the limits of funds available to those approved applicants whose projects will best promote the purposes of section 797 of the Act.

§ 58.506 How long does grant support last?

(a) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, may not exceed three years for an Allied Health Advanced Traineeship grant, and may not exceed one year for an Allied Health Training Institute grant.

(b) For Allied Health Advanced Traineeship grants, generally the grant will initially be funded for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of factors such as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(d) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 58.507 How is the amount of the award determined?

The amount of the award to the grantee will be based on the Secretary's estimate of the sum necessary during the budget period to cover the costs of the trainees' tuition, fees, stipends, and allowances (including travel and subsistence).

§ 58.508 For what purposes may grant funds be spend?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instructions or for any religious purpose.

§ 58.509 What financial support is available to trainees?

(a) The grantee may pay to the trainee:

(1) Tuition and fees in accordance with the established rates of the institution, except as limited by the Secretary.

(2) Stipends, in whatever amount the grantee determines that each trainee needs to pursue the training program, as long as that amount does not exceed the limits established by the Secretary.

(3) Transportation allowances on an individual basis when prior approval has been obtained from the Secretary in the circumstances described in paragraph (b) of this section.

(b) For Allied Health Advanced Traineeship grants:

(1) In cases of extreme need, the grantee may pay a trainee an allowance from grant funds for travel from his or her residence to the training site.

(2) The grantee may pay a trainee an allowance from grant funds for travel to field training if the site is beyond a reasonable commuting distance and requires the trainee to establish a temporary new residence. However, the grantee may not pay an allowance for daily commuting from the new place of residence to the field training headquarters.

(3) The grantee may pay a trainee an allowance from grant funds for domestic travel to conduct research to meet dissertation requirements.

(c) For Allied Health Training Institute programs:

(1) The grantee may pay stipends from grant funds only to trainees who must temporarily change their place of residence to attend the training program.

(2) The grantee may pay stipends from grant funds only for days of instruction during which the trainee receives a minimum of six hours of formal instruction, except that during the first and last days of the training session the trainee must receive a minimum of three hours during the day.

(3) The grantee may not pay stipends from grant funds to a trainee

receiving concurrent support for the same training from another Federal source, except education benefits under the Veterans Readjustment Benefits Act.

§ 58.510 Who is eligible for financial assistance as a trainee?

(a) To be eligible for a traineeship, an individual must:

(1) Be a national of the United States or a lawful permanent resident of the United States, Puerto Rico, the Virgin Islands, Guam or a permanent resident of the Trust Territory of the Pacific Islands or the Northern Mariana Islands;

(2) Be accepted for enrollment, or be enrolled, as a full-time student in a training program for which these traineeships are available;

(3) Not be the program director, financial officer, or the official authorized to represent the grantee institution for the grant application;

(4) Not be receiving lecture fees, salary, travel, expenses, or any other form of payment as a member of the grantee training program staff or faculty.

(b) For the Allied Health Advanced Traineeship program:

(1) Be qualified to practice as one of the following:

Clinical Psychologist
Dental Assistant
Dental Hygienist
Dental Laboratory Technician
Dietitian[1]
Medical Assistant
Medical Record Administrator
Medical Technologist[2]
Nuclear Medicine Technologist
Occupational Therapist
Physical Therapist
Primary Care Physician Assistant
Radiation Therapy Technologist
Radiographer
Respiratory Therapist
Sanitarian[3]
Speech Pathologist/Audiologist
Vision Care Technician[4]

(2) Have a baccalaureate degree;

(3) Not be receiving concurrent support for the same training from another Federal source except education benefits under the Veterans Readjustment Benefits Act;

(4) Not be a full-time Federal employee unless on leave without pay.

(c) For the Allied Health Training Institute program:

(1) Be qualified to practice as one of the following:

Clinical Psychologist
Cytotechnologist
Dental Assistant
Dental Hygienist
Dental Laboratory Technician
Dietitian[5]
Medical Assistant
Medical Laboratory Technician
Medical Record Administrator
Medical Record Technician
Medical Technologist[6]
Nuclear Medicine Technologist
Occupational Therapist
Occupational Therapy Assistant
Orthotic/Prosthetic Technician
Physical Therapist
Physical Therapist Assistant
Primary Care Physician Assistant
Radiation Therapy Technologist
Radiographer
Respiratory Therapy Technician/Therapist
Sanitarian[7]
Speech Pathologist/Audiologist
Vision Care Technician[8]

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[1] Limited to graduates of a coordinated undergraduate program and those persons having completed a clinical dietetic internship or other clinical practicum training acceptable to the Secretary.

[2] Limited to persons qualified as medical technologists whether or not employed in a specialty area and does not include persons qualified only in a clinical laboratory specialty.

[3] Limited to graduates of baccalaureate level educational programs or to those who are State registered sanitarians or possess the professional qualifications necessary for registration under any of the State registration acts.

[4] Includes persons prepared as an opthalmic medical assistant, optometric technician, low vision technician, orthoptist, contact lens technician.

[5] Same as [1].

[6] Same as [2].

[7] Same as [3].

[8] Includes persons prepared as an opthalmic assistant, ophthalmic dispenser, opthalmic optician, optometic technician, low vision technician, orthoptist, and contact lens technician.

§ 58.511 What are the requirements for traineeships and the appointment of trainees?

(a) For the Allied Health Advanced Traineeship program:

(1) The grantee must appoint each trainee for a full academic year (not to exceed twelve months) except that a shorter appointment may be made where necessary to enable the trainee to complete the training program.

(2) The grantee must require each trainee to complete a statement of appointment by the beginning of the training period or as soon as possible if the trainee receives notice after the training period has begun. The program director must sign it, and the grantee must retain it for audit purposes. The grantee must also send a copy to the Secretary upon request.

(3) The grantee must advise each trainee who is enrolled in a course of study requiring more than twelve months to complete that continued support under this program is contingent upon the continued availability of grant funds.

(b) For the Allied Health Training Institute program, the grantee's appointment for each trainee must be effective the first day of required attendance and must terminate on the last day of each offering or session of the institute.

(c) The grantee may not require trainees to perform any work which is not an integral part of their training program and required of all students in the program, or to perform services which detract from or prolong the training.

§ 58.512 Termination of traineeship.

(a) The grantee will terminate a traineeship upon request of the trainee.

(b) The grantee must terminate the traineeship if the trainee is no longer enrolled full-time in the training program for which the traineeship was awarded, or fails to maintain the level of academic standing required by the institution's standards and practices for full-time enrollment.

§ 58.513 What additional Department regulations apply to grantees?

Several other regulations apply to these grants. They include, but are not limited to:

42 CFR Part 50	PHS grant appeals process
45 CFR Part 16	Department grant appeals process
45 CFR Part 46	Protection of human subjects
45 CFR Part 74	Administration of grants
45 CFR Part 80	Nondiscrimination under programs receiving Federal assistance through the Department—Implements Title VI of the Civil Rights Act of 1964
45 CFR Part 81	Practice and procedure for hearings under Part 80
45 CFR Part 83	Nondiscrimination on the basis of sex in the admission of individuals to training programs
45 CFR Part 84	Nondiscrimination on the basis of handicap in Federally assisted programs
45 CFR Part 86	Nondiscrimination on the basis of sex in Federally assisted education programs
45 CFR Part 91[9]	Nondiscrimination on the basis of age in Department programs or activities receiving Federal financial assistance.

§ 58.514 What other audit and inspection requirements apply to grantees?

Each grantee must, in addition to the requirements of 45 CFR Part 74, meet the requirements of section 705 of the Act, concerning audit and inspection.

§ 58.515 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of an award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

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[9] When issued.

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

Sec.

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Subpart A—Project Grants for Family Planning Services

AUTHORITY: Sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-4; sec. 6(c), 84 Stat. 1506, 42 U.S.C. 300.

SOURCE: 45 FR 37436, June 3, 1980, unless otherwise noted.

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

§ 59.2 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Family" means a social unit composed of one person, or two or more persons living together, as a household.

"Low income family" means a family whose total annual income does not exceed 100 percent of the most recent Community Services Administration Income Poverty Guidelines (45 CFR 1060.2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

"Nonprofit," as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, Northern Marianas, or the Trust Territory of the Pacific Islands.

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, such as natural family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other service, assistance from or participation in any other program of the applicant.[1]

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide abortions as a method of family planning.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a Government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent CSA Income Poverty Guidelines (45 CFR 1060.2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

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[1] Section 205 of Pub. L. 94-63 states: "Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both."

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX or title XX of the Social Security Act, a written agreement with the title XIX or title XX agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by § 59.6.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to (i) achieve community understanding of the objectives of the program, (ii) inform the community of the availability of services, and (iii) promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and inservice training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and methods of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurances satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of population or community for which the materials are intended.

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which it is to be made available; and

(v) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the Federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent of the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3 to 5 years.

(b) Generally the grant will initially be for 1 year and subsequent continuation awards will also be for 1 year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

§ 59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

42 CFR Part 50—PHS Informal Grant Appeals Procedure

45 CFR Part 16—Department Grant Appeals Process

45 CFR Part 19—Limitation on Payments or Reimbursements for Drugs

45 CFR Part 74—Administration of Grants

45 CFR Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services' Implementation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and Procedures for Hearings Under Part 80

45 CFR Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance

45 CFR Part 90—Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance

42 CFR Part 122, Subpart E—Health System Agency Reviews of Certain Proposed Uses of Federal Health Funds

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Inventions or discoveries.

(a) A project grant award is subject to the regulations of HHS as set forth in 45 CFR Parts 6 and 8, as amended. These regulations shall apply to any activity of the project for which grant funds are used, whether the activity is part of an approved project or is an unexpected byproduct of that project.

(b) The grantee and the Secretary shall take appropriate measures to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the grant activity are aware of and comply with such obligations.

§ 59.13 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

Subpart B—[Reserved]

Subpart C—Grants for Family Planning Service Training

AUTHORITY: Sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-4; sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-1.

SOURCE: 37 FR 7093, Apr. 8, 1972, unless otherwise noted.

§ 59.201 Applicability.

The regulations in this subpart are applicable to the award of grants pursuant to section 1003 of the Public Health Service Act (42 U.S.C. 300a-1) to provide the training for personnel to carry out family planning service programs described in sections 1001 and 1002 of the Public Health Service Act (42 U.S.C. 300, 300a).

§ 59.202 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act.

(b) "State" means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, or the Trust Territory of the Pacific Islands.

(c) "Nonprofit" private entity means a private entity no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(d) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(e) "Training" means job-specific skill development, the purpose of which is to promote and improve the delivery of family planning services.

§ 59.203 Eligibility.

(a) *Eligible applicants.* Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart.

(b) *Eligible projects.* Grants pursuant to section 1003 of the Act and this subpart may be made to eligible applicants for the purpose of providing programs, not to exceed three months in duration, for training family planning or other health services delivery personnel in the skills, knowledge, and attitudes necessary for the effective delivery of family planning services: *Provided,* That the Secretary may in particular cases approve support of a program whose duration is longer than three months where he determines (1) that such program is consistent with the purposes of this subpart and (2) that the program's objectives cannot be accomplished within three months because of the unusually complex or specialized nature of the training to be undertaken.

[37 FR 7093, Apr. 8, 1972, as amended at 40 FR 17991, Apr. 24, 1975]

§ 59.204 Application for a grant.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.[1] The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

§ 59.205 Project requirements.

An approvable application must contain each of the following unless the Secretary determines that the applicant has established good cause for its omission:

(a) Assurances that:

(1) No portion of the Federal funds will be used to train personnel for programs where abortion is a method of family planning.

(2) No portion of the Federal funds will be used to provide professional training to any student as part of his education in pursuit of an academic degree.

(3) No project personnel or trainees shall on the grounds of sex, religion, or creed be excluded from participation in, be denied the benefits of, or be

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[1] Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of the Director, National Center for Family Planning Services, Health Services and Mental Health Administration, Rockville, MD 20852 for national programs.

subjected to discrimination under the project.

(b) Provision of a methodology to assess the particular training (e.g., skills, attitudes, or knowledge) that prospective trainees in the area to be served need to improve their delivery of family planning services.

(c) Provision of a methodology to define the objectives of the training program in light of the particular needs of trainees defined pursuant to paragraph (b) of this section.

(d) Provision of a method for development of the training curriculum and any attendant training materials and resources.

(e) Provision of a method for implementation of the needed training.

(f) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program.

(g) Provision of a method and criteria by which trainees will be selected.

§ 59.206 Evaluation and grant award.

(a) Within the limits of funds available for such purpose, the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 1003 of the Act, taking into account:

(1) The extent to which a training program will increase the delivery of services to people, particularly low-income groups, with a high percentage of unmet need for family planning services;

(2) The extent to which the training program promises to fulfill the family planning services delivery needs of the area to be served, which may include, among other things:

(i) Development of a capability within family planning service projects to provide pre- and in-service training to their own staffs;

(ii) Improvement of the family planning services delivery skills of family planning and health services personnel;

(iii) Improvement in the utilization and career development of paraprofessional and paramedical manpower in family planning services;

(iv) Expansion of family planning services, particularly in rural areas, through new or improved approaches to program planning and deployment of resources;

(3) The capacity of the applicant to make rapid and effective use of such assistance;

(4) The administrative and management capability and competence of the applicant;

(5) The competence of the project staff in relation to the services to be provided; and

(6) The degree to which the project plan adequately provides for the requirements set forth in § 59.205.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (1) On the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) Allowability of costs shall be in conformance with the applicable cost principles prescribed by Subpart Q of 35 CFR Part 74.

(d) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.207 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 59.208 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with the statute, the regulations of this subpart, the terms and conditions of the award, and, except as may otherwise be provided in this subpart, the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

(b) Prior approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

(c) The Secretary may approve the payment of grant funds to trainees for:

(1) Return travel to the trainee's point of origin.

(2) Per diem during the training program, and during travel to and from the program, at the prevailing institutional or governmental rate, whichever is lower.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.209 Civil rights.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation impelmenting such Title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR Part 80).

§ 59.210 Inventions or discoveries.

Any grant award pursuant to § 59.206 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR Parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§ 59.211 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 59.212 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) [Reserved]

(c) *Accounting for grant-related income*—(1) *Interest.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(d) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (c)(1) of this section;

(iii) Any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

[36 FR 18465, Sept. 15, 1971, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.213 [Reserved]

§ 59.214 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

§ 59.215 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to all other grantee organizations under this subpart.

45 CFR PART 74

Subpart:

A	General.
B	Cash Depositories.
C	Bonding and Insurance.
D	Retention and Custodial Requirements for Records.
F	Grant-Related Income.
G	Matching and Cost Sharing.
K	Grant Payment Requirements.
L	Budget Revision Procedures.
M	Grant Closeout, Suspension, and Termination.
O	Property.
Q	Cost Principles.

[38 FR 26199, Sept. 19, 1973]

PART 59a—NATIONAL LIBRARY OF MEDICINE GRANTS

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

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59a.12 Definitions.
59a.13 Application.
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Subpart B—Grants for Establishment of Regional Medical Libraries

59a.31 Applicability.
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59a.39 Publications.

SOURCE: 45 FR 12250, Feb. 25, 1980, unless otherwise noted.

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

AUTHORITY: Sec. 392, 79 Stat. 1060, as amended, 84 Stat. 66, 67, 88 Stat. 372 (42 U.S.C. 280b-2); sec. 395, 79 Stat. 1063, as amended, 84 Stat. 63-67, 87 Stat. 92, 88 Stat. 372, 373 (42 U.S.C. 280b-7).

§ 59a.11 Applicability.

The provisions of this subpart apply to grants for establishing, expanding, and improving basic resources as authorized by section 395 of the Public Health Service Act.

§ 59a.12 Definitions.

(a) All terms not defined herein shall have the same meaning given them in the Act.

(b) "Act" means the Public Health Service Act, as amended (42 U.S.C. 201 et seq.).

(c) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(d) "Related instrumentality" means a public or private nonprofit institution, organization, or agency other than a library whose primary function is the acquisition, preservation, dissemination, and/or processing of information relating to the health sciences.

§ 59a.13 Application.

Any public or private nonprofit institution, organization, or agency authorized or qualified to carry on the functions of a medical library or related instrumentality may file an application for a grant of money or materials, or both. Application for grant under this subpart shall be made on an authorized form.

§ 59a.14 Evaluation of applications.

All applications filed in accordance with § 59a.13 shall be evaluated by the Secretary through such officers and employees of the Service and such experts, consultants, or groups as the Secretary may engage for this purpose. In addition to such other factors as may be required by the Act or the regulations of this subpart, the Secretary's evaluation shall take into account the scope of library or related services in relation to the population and purposes served by the library or related instrumentality as may be pertinent, including evidence of the efficiency of the applicant in providing services, the amount of available equipment and other resources on hand to satisfy the needs of the area served by the facility, coordination with other library and related facilities, and potentiality for testing or demonstration of new or improved techniques in health sciences informational services.

§ 59a.15 Grant awards.

(a) *General.* Within the limits provided by law and to the extent of funds available, the Secretary shall award grants to those applicants whose proposals for establishment, expansion, or improvement will in the Secretary's judgment best promote the purposes of section 395 of the Act.

(b) *Determination of award amount.* The amount of any award, not to exceed $200,000, shall be determined by the Secretary:

(1) On the basis of the scope of medical library or related services provided by the applicant in relation to the population and purposes served by it, taking into account the following factors:

(i) The number of graduate and undergraduate students, and physicians and other practitioners in the sciences related to health making use of the applicant's library resources;

(ii) The type of supportive staffs, if any, available to the applicant's library;

(iii) The type, size, and qualifications of the faculty of any school with which the applicant is affiliated;

(iv) The staff of any hospitals or clinics with which the applicant's library is affiliated;

(v) The geographic area served by such applicant and the availability, within such area, of medical library or related services provided by other libraries or related instrumentalities; and

(2) Shall be in such amount as in the Secretary's judgment will assure adequate continuing financial support of the applicant's proposed activity from other sources during and after the period of award. In making such determination, the Secretary shall take into consideration the level of non-Federal support for the proposed activity for periods prior to the fiscal year in which a grant is made and shall require assurance from the applicant that such support will not be diminished as a result of such award and that adequate support for such activity will be continued during and after the period of Federal Assistance: *Provided,* That subject to such exceptions as the Secretary may determine to be necessary for the orderly administration of the grant program hereunder, no grant shall be made for less than $1,000.

(c) *Project period.* (1) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 1-5 years.

(2) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(3) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award for any approved application or portion of an approved application.

§ 59a.16 [Reserved]

§ 59a.17 Use of funds or materials.

Any funds or materials provided by a grant pursuant to this subpart shall be expended or utilized by the grantee solely for the purposes for which the funds or materials were granted, in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74. The grantee may not in whole or in part delegate or transfer this responsibility to any other person.

§ 59a.18 Inventions or discoveries.

Any grant award hereunder is subject to the regulations of the Department of Health and Human Services relating to inventions and patents (45 CFR Parts 6 and 8, as amended). Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligation.

§ 59a.19 Other HHS regulations that apply.

Several other regulations apply to grants under this subpart. These include but are not limited to:

42 CFR Part 50—PHS grant appeals procedure.

45 CFR Part 16—Department grant appeals process.

45 CFR Part 74—Administration of grants.

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates, and other cost allocations).

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964.

45 CFR Part 81—Practice and procedure for hearings under Part 80.

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance.

Subpart B—Grants for Establishment of Regional Medical Libraries

AUTHORITY: Sec. 392, 79 Stat. 1060, as amended, 84 Stat. 66, 67, 88 Stat. 372 (42 U.S.C. 280b-2); sec. 396, 79 Stat. 1065, as amended, 84 Stat. 63, 65, 67, 87 Stat. 92, 88 Stat. 372, 373 (42 U.S.C. 280b-8).

§ 59a.31 Applicability.

The provisions of this subpart apply to grants to public or private nonprofit institutions authorized and qualified to carry on the functions of a medical library to establish and maintain regional medical libraries for the geographic areas in which they are located as authorized by section 396 of the Public Health Service Act.

§ 59a.32 Definitions.

(a) All terms not defined herein shall have the same meaning given them in the Act;

(b) "Act" means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*);

(c) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated;

(d) "Geographic area" means an area composed of any part or parts of any one or more states that forms an academically and professionally integrated region, taking into consideration such factors as location and extent of communication facilities and systems, presence and distribution of educational and medical and health facilities and programs, and other activities which, in the opinion of the Secretary, justify the establishment and operation of a regional medical library;

(e) "Annual operating expenses" means, with respect to a library which has been in operation for less than 3 years an amount equal to the average annual operating expense of the years, if any, of operation, as modified by, or when there has been no operation determined by reference to, such expense of libraries of institutions of similar size and function, as determined by the Secretary;

(f) "Modify and increase" means the use of Federal funds or materials to supplement rather than supplant non-Federal funds available for library resources and services.

§ 59a.33 Eligibility.

In order to be eligible for a grant, the applicant must:

(a) Meet the criteria specified in section 396 of the Act, and

(b) Be located in a State.

§ 59a.34 Application.

(a) Application for a grant under this subpart shall be made on an authorized form;

(b) In addition to any other pertinent information which the Secretary may require, the applicant shall submit a description of a program to provide health sciences informational services for the geographic area in which it is located in sufficient detail clearly to identify the need for such services, the adequacy of the applicant's existing or proposed facilities and resources to undertake to provide them, the size and nature of the population to be served, the region to be served, cooperative arrangements in effect, or proposed, with other qualified institutions, organizations or agencies, and the justification for the amount of funds requested.

§ 59a.35 Award.

(a) *General.* The Secretary, with the counsel and advice of the Board in each case, shall award a grant to those applicants whose arrangements and proposed services will in the Secretary's judgment best promote the purpose of section 396 of the Act.

(b) *Project period.* (1) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 1-5 years.

(2) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(3) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award for any approved application or portion of an approved application.

§ 59a.36 Other HHS regulations that apply.

Several other regulations apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50—PHS grant appeals procedure.

45 CFR Part 16—Department grant appeals process.

45 CFR Part 74—Administration of grants.

45 CFR Part 75—Informal grant appeals procedure (indirect cost rates and other cost allocations).

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964.

45 CFR Part 81—Practice and procedure for hearings under Part 80.

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from federal financial assistance.

[45 FR 12250, Feb. 25, 1980; 45 FR 20097, Mar. 27, 1980]

§ 59a.37 Terms, conditions, and assurances.

In addition to any other terms, conditions, and assurances required by law or imposed by the Secretary, each grant shall be subject to the following terms, conditions, and assurances to be furnished by the applicant. The Secretary may at any time approve exceptions where the Secretary finds that such exceptions are not inconsistent with the Act and the purposes of the program.

(a) *Use of funds.* Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

(b) *Service undertakings.* (1) The grantee will agree to modify and increase its library resources so as to be able to provide supportive services to other health sciences informational activities.

(2) Qualified persons and organizations shall be entitled to free loan services, and to the extent grant funds are used to provide photo duplicated or facsimile copies of biomedical materials, the copies shall be made available without charge to such persons or organizations. The qualification of persons and organizations for the services provided hereunder shall be determined in accordance with the policies or principles of operation of the grantee, subject to such review and approval as the Secretary may require.

(c) *Inventions or discoveries.* Any grant award hereunder is subject to the regulations of the Department of Health and Human Services relating to inventions and patents (45 CFR Parts 6 and 8, as amended). Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the program as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments, or other arrangements, inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligation.

[45 FR 12250, Feb. 25, 1980; 45 FR 20097, Mar. 27, 1980]

§ 59a.38 Termination. [Reserved]

§ 59a.39 Publications.

Grantees may publish materials relating to their regional medical library without prior review, providing such publications carry a footnote acknowledging assistance from the Public Health Service and indicating that findings and conclusions do not necessarily represent the views of the Service.

PART 60—HEALTH EDUCATION ASSISTANCE LOAN PROGRAM

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60.60 School audits.

AUTHORITY: Title VII, part C, subpart I of the Public Health Service Act, as amended, 90 Stat. 2243 (42 U.S.C. 294-294*l*), unless otherwise noted.

SOURCE: 43 FR 34324, Aug. 3, 1978, unless otherwise noted. Redesignated at 46 FR 8519, Jan. 27, 1981.

Subpart A—General Program Description

§ 60.1 What is the HEAL program?

(a) The health education assistance loan (HEAL) program is a program of Federal insurance of educational loans designed for students in the fields of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, pharmacy, and public health. The basic purpose of the program is to encourage lenders to make loans to students in these fields who desire to borrow money to pay for their educational costs. In addition, certain nonstudents (such as doctors serving as interns or residents) can borrow in order to pay the current interest charges accruing on earlier HEAL loans.

(b) Schools, State agencies, pension funds, banks and other financial institutions having an insurance contract with the Commissioner of Education can be lenders under the HEAL program. HEAL lender eligibility is described in § 60.30. HEAL school eligiblility is described in § 60.50.

(c) By taking a HEAL loan, the student obligates himself or herself to repay the lender the full amount of the money borrowed, plus all interest which accrues on the loan. Depending upon the specific agreement between the borrower and the lender, the borrower may have to pay the lender while in school for the interest that accrues on the loan during that period. Other lenders may permit the borrower to defer all payments towards interest until the borrower is out of school.

(d) Generally, repayment of principal is not required until the first day of the tenth month after the month the student has left school or completed a period of internship or residency or both. After the repayment period has commenced, a borrower may defer repayment of principal for a limited period while serving in the Armed Forces, the Peace Corps, VISTA, the National Health Service Corps, or an internship or residency program, or during a period in which the borrower has returned to school as a fulltime student.

(e) The Commissioner of Education insures each lender for the losses it may incur in the event that a borrower dies, becomes disabled, files bankruptcy, or defaults on his or her loan. If a borrower defaults on a loan and the Commissioner pays the amount of loss to the lender, the borrower's loan is then assigned to the Commissioner. At that time, the U.S. Government becomes the borrower's direct creditor and will actively pursue the borrower for repayment of the debt.

(f) The law also provides that a borrower's loan may not be discharged in bankruptcy until after the first 5 years of the repayment period. A defaulted borrower practicing his or her profession is subject to having medicare or medicaid payments withheld up to the amount of the loan.

(g) The Commissioner of Education may enter into a special contract with a borrower who has obtained a degree from a HEAL school. Under the contract, the borrower agrees to serve for at least 2 years in a health manpower shortage area as a member of the National Health Service Corps or as a private practitioner. In return, the Commissioner agrees to pay an amount, not to exceed $10,000 per year, to the holder of the borrower's HEAL loan to be applied toward interest and principal.

(h) The determination of health manpower shortage areas will be made by the Secretary. The availability of any contracts for any year is not assured and is limited by the size of the nation's health manpower shortages in the various health disciplines, and the appropriation of funds for this purpose. An individual may receive a contract only at the Commissioner's discretion. In addition, and except in cases of impossibility or extreme hardship, severe penalties are provided in the law for any borrower who does not comply with the terms of the contract.

(42 U.S.C. 294-294*l*)

Subpart B—The Borrower

§ 60.5 Who is an eligible student borrower?

In order to receive a HEAL loan, a student must satisfy the following requirements:

(a) He or she must be:

(1) A citizen, national or permanent resident of the United States; or

(2) A permanent resident of the Trust Territory of the Pacific Islands or the Northern Mariana Islands; or

(3) In the United States for other than a temporary purpose and intend to become a permanent resident.

(b) He or she must be enrolled or accepted for enrollment at a HEAL school in a course of study that leads to one of the following degrees:

Doctor of Medicine.
Doctor of Osteopathy.
Doctor of Dentistry or equivalent degree.
Doctor of Veterinary Medicine or equivalent degree.
Doctor of Optometry or equivalent degree.
Doctor of Podiatry or equivalent degree.
Bachelor or Master of Science in Pharmacy or equivalent degree.
Graduate or equivalent degree in Public Health.

(c) He or she must be carrying or plan to carry, during the period for which the loan is intended, the normal workload of a full-time student, as determined by the school. The student's work load may include any combination of courses, work experience, research or special studies that the school considers sufficient to classify the student as full-time.

(d) If currently enrolled in school, he or she must be in good standing, as determined by the school.

(e) In the case of a pharmacy student, he or she must have satisfactorily completed 3 years of training toward the pharmacy degree. These 3 years of training may have been taken at the pharmacy school or at a different school whose credits are fully accepted on transfer by the pharmacy school.

(f) In the case of a medical, dental or osteopathic student enrolled in a 6-year program that the student enters directly from secondary school, the student must be enrolled in the last 4 years of the program.

(g) [Reserved]

(h) He or she must agree that all funds received under the proposed loan will be used solely for tuition and other reasonable educational expenses, including room and board, fees, books, supplies and equipment, laboratory expenses, transportation and commuting costs, personal expenses, the HEAL insurance premium, and interest on HEAL loans.

(42 U.S.C. 294b, 294d, 294h, 294j)

[43 FR 34324, Aug. 3, 1978. Redesignated and amended at 46 FR 8519, Jan. 27, 1981]

§ 60.6 Who is an eligible nonstudent borrower?

In order to receive a HEAL loan, a person who is not a student must satisfy all of the following requirements:

(a) He or she must have previously received a HEAL loan for which he or she is required to make payments of interest, but not principal, during the period for which the new loan is intended. This may be the grace period or a period of internship, residency or deferment.

(b) He or she must continue to meet the citizen, national, or residency qualifications required of student borrowers.

(c) He or she must agree that all funds received under the proposed loan will be used solely for payment of currently accruing interest on HEAL loans and the HEAL insurance premium.

(42 U.S.C. 294d, 294h)

§ 60.7 The loan application process.

(a) A person seeking a HEAL loan must accurately and completely fill out the loan application form provided by the lender. In the case of a student borrower, the student borrower must complete a portion of the application form and must have his or her school complete another portion. The school provides information relating to the student's eligibility, the student's estimated cost of attendance, and other financial aid (exclusive of family contributions) which the school is aware will be awarded the student during the academic period covered by the proposed HEAL loan.

(b) A special requirement exists for students enrolled or accepted for enrollment in courses of study leading to a degree in medicine, osteopathic medicine, or dentistry. For these students, the school must additionally state on the loan application that it authorizes the loan applicant to receive a HEAL loan. Schools of medicine, osteopathic medicine and dentistry are responsible for making sure that no more than 50 percent of their students in each class are authorized to receive new HEAL loans each academic year.

(c) If the lender agrees to make the loan to the applicant, and if the Commissioner of Education approves the loan for HEAL insurance, the applicant then must sign a promissory note. The promissory note sets out the rights and responsibilities of the borrower and lender. Subpart C of these regulations describes the terms of the loan in detail.

(42 U.S.C. 294d, 294h, 294*l*)

[43 FR 34324, Aug. 3, 1978. Redesignated and amended at 46 FR 8519, Jan. 27, 1981]

§ 60.8 What are the borrower's major rights and responsibilities?

(a) *The borrower's rights.* (1) Once the terms of the HEAL loan have been established, the lender may not change them without the borrower's consent.

(2) The lender must provide the borrower with a copy of the completed promissory note when the loan is made. The lender must return the original note to the borrower when the loan is paid in full.

(3) The lender must make the HEAL loan disbursement check or draft payable to the borrower or, if authorized by the borrower in writing, jointly to the borrower and the school. The loan disbursement check or draft must require the personal endorsement of the borrower.

(4) The lender must provide the borrower with a copy of the repayment schedule before repayment begins.

(5) If the loan is sold from one lender to another lender, or if the loan is serviced by a party other than the lender, the holder must notify the borrower if the borrower is required to send installment payments or direct other matters connected with the loan to a new address.

(6) The borrower does not have to begin repayment until nine full months after leaving school or an accredited internship or residency program as more fully described in § 60.11.

(7) The borrower is entitled to deferment from repayment of the principal amount of his or her loans during certain periods as more fully described in § 60.12.

(8) The borrower may prepay the whole or any portion of the loan at any time without penalty.

(9) The borrower's total loan obligation is cancelled in the event of death or total and permanent disability.

(10) In order to assist the borrower in avoiding default, the lender may grant the borrower forbearance. However, whether or not to grant forbearance is wholly within the lender's discretion. Forbearance is more fully described in § 60.37.

(11) At the option of the Federal Government, the borrower may apply for a special contract to have his or her loan fully or partially repaid by serving for at least 2 years in a health manpower shortage area determined by the Secretary. A contract may be granted depending on the availability of the various health manpower positions in shortage areas at the time repayment is due and the availability of funds appropriated for this purpose.

(b) *The borrower's responsibilities.* (1) The borrower must become familiar with the terms of the loan, including the manner in which interest is payable over the life of the loan.

(2) The borrower must pay any insurance premium that the lender may require as more fully described in § 60.14.

(3) The borrower must pay all interest charges on the loan as required by the lender.

(4) The borrower must immediately notify the lender if any of the following occurs:

(i) Change of address;

(ii) Change of name;

(iii) Failure to enroll in a HEAL school for the period for which the loan is intended;

(iv) Transfer to another school;

(v) Withdrawal from a HEAL school or change in status to less than full-time attendance at a HEAL school;

(vi) Graduation;

(vii) Cessation of participation in an internship or residency program;

(viii) Change of status that entitles a borrower to deferments; and

(ix) Change of status that authorized deferment of loan.

(5) The borrower must repay the loan in accordance with the repayment schedule. A borrower may not

have a HEAL loan discharged in bankruptcy until after the first 5 years of the repayment period.

(6) If the borrower fails to make payments on the loan on time, the total amount to be repaid by the borrower may be increased by additional interest, late charges, attorney's fees, court costs, and other collection charges. In addition, the United States may offset amounts attributable to an unpaid loan from Federal reimbursements for medicaid or medicare to a defaulted borrower practicing his or her profession.

(42 U.S.C. 294d, 294e, 294f, 294h, 294k)

Subpart C—The Loan

§ 60.10 How much can be borrowed?

(a) *Student borrower.* An eligible student borrower may borrow an amount for an academic year equal to the difference between: (1) The student's cost of education for that period as defined in § 60.5(h); and (2) the amount of other student aid he or she will receive for that period within the following limitations:

(i) A student enrolled in a school of medicine, osteopathic medicine, or dentistry may borrow $50,000 under this part, or up to $60,000 if the student's costs, as described in § 60.5(h), justify this amount. This amount received may not exceed $15,000 per academic year.

(ii) A student enrolled in a school of veterinary medicine, optometry, podiatry, or public health may borrow up to $50,000 under this part. This amount received may not exceed $10,000 per academic year.

(iii) A student enrolled in a pharmacy school may borrow up to $37,500 under this part. This amount received may not exceed $7,500 per academic year.

(iv) For purposes of this paragraph, an academic year means the traditional approximately 9-month September to June annual session. For the purpose of computing academic year equivalents for students who, during a 12-month period, attend for a longer period than the traditional academic year, the academic year will be considered to be 9 months in length.

(b) *Nonstudent borrower.* An eligible nonstudent may borrow amounts under this authority with the following restrictions:

(1) In no case may an eligible nonstudent borrower receive a loan that is greater than the sum of the HEAL insurance premium plus the interest that is expected to accrue and must be paid on the borrower's HEAL loans during the period for which the new loan is intended.

(2) An eligible nonstudent in the field of medicine, osteopathic medicine, or dentistry may borrow up to $50,000 under this part including loans obtained while the borrower was a student, or $60,000, if the borrower's costs require this increase. The loan amount may not exceed $15,000 per 12-month period.

(3) An eligible nonstudent in the field of pharmacy may borrow up to $37,500 under this authority, including loans obtained while the borrower was a student. The loan amount received under this part may not exceed $7,500 per 12-month period.

(4) An eligible nonstudent in the field of veterinary medicine, optometry, podiatry or public health may borrow under this authority up to $50,000, including loans obtained while the borrower was a student. The loan amount received under this part may not exceed $10,000 per 12-month period.

(Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 729 of the Public Health Service Act, 93 Stat. 582 (42 U.S.C. 294c))

[46 FR 8519, Jan 27, 1981]

§ 60.11 Terms of repayment.

(a) *Commencement of repayment.* The borrower's repayment period must begin the first day of the 10th month after the month he or she ceases to be a full-time student at a HEAL school. However, if the borrower becomes an intern or resident in an accredited program within 9 full months after leaving school, then the borrower's repayment period must begin the first day of the 10th month after the month he or she ceases to be an intern or resident. The 9-month period before the repayment period begins is popularly called the "grace period." If a nonstudent borrower obtains another another HEAL loan during the grace period or a period of internship, residency, or deferment, the borrower must begin to repay this loan when repayment on the borrower's other HEAL loans begins or resumes.

(b) *Length of the repayment period.* In general, a lender must allow a borrower at least 10 years, but not more than 15 years, to repay a loan calculated from the beginning of repayment period. A borrower must fully repay a loan within 23 years after it is made. There is an exception, however, to these rules. If a borrower receives a deferment from repayment, as more fully described in § 60.12, the period of the deferment is not included in the calculation of the 10-, 15-, and 23-year periods.

(c) *Prepayment.* A borrower may repay the whole or any part of a loan before required by the repayment schedule. A borrower who prepays a loan may not be penalized in any way by the holder of the loan.

(d) *Minimum annual payment.* During each year of repayment, a borrower's payments to all holders of his or her HEAL loans must total at least $600 or a sum equal to the interest that accrues during the year on all of the loans, whichever amount is greater. However, the $600 rule does not apply in any case where it would result in a borrower repaying a HEAL loan in fewer than 10 years.

(e) *Repayment schedule agreement.* During the grace period, a borrower must contact the holder of the loan to establish the precise terms of repayment. The repayment schedule may provide for substantially equal installment payments or for installment payments that increase in amount over the repayment period. If a graduated repayment schedule is established, it may not provide for any single installment that is more than five times greater than any other installment.

(f) *Supplemental repayment agreement.* (1) A lender and a borrower may enter into an agreement supplementing the regular repayment schedule agreement. Under a supplemental repayment agreement, the lender agrees that the borrower is deemed to meet the terms of the regular repayment schedule so long as the borrower makes payments in accordance with a separate schedule.

(2) The purpose of a supplemental repayment agreement is to permit a lender, at its option, to offer a borrower a repayment schedule based on other than equal or graduated payments. (For example, a supplemental repayment agreement may base the amount of the borrower's payments on his or her income.)

(3) The agreement and separate schedule must contain terms which the Commissioner of Education is satisfied do not unduly burden the borrower and do not subject the Commissioner to undue liability. A lender and borrower may not enter into a supplemental repayment agreement unless the lender has obtained the Commissioner's prior approval of its terms.

(4) The borrower may not insist upon the establishment of a supplemental repayment agreement. The lender may not insist upon the establishment of a supplemental repayment agreement unless the borrower's written consent to enter into an agreement of this type was obtained by the lender at the time the loan was made.

(5) A lender may assign a loan subject to a supplemental repayment agreement only if it makes the buyer aware of the terms of the supplemental agreement. In such cases, the loan and the supplemental agreement must be assigned together.

(42 U.S.C. 294d, 294h)

§ 60.12 Deferment.

(a) Once the repayment period has commenced, periodic installments of principal may be deferred during any period:

(1) During which the borrower is pursuing a full-time course of study at a HEAL school or at an institution of higher education that is a "participating school" in the guaranteed student loan program; or

(2) Not in excess of 3 years during which the borrower is a participant in an accredited internship or residency program; or

(3) Not in excess of 3 years during which the borrower is a member of the Armed Forces of the United States; or

(4) Not in excess of 3 years during which the borrower is in service as a volunteer under the Peace Corps Act; or

(5) Not in excess of 3 years during which the borrower is a member of the National Health Service Corps; or

(6) Not in excess of 3 years during which the borrower is a full-time volunteer under title I of the Domestic Volunteer Service Act of 1973.

(b) In order to receive a deferment, a borrower must apply to the holder of the loan. If the borrower submits written evidence that verifies eligibility for the deferment, the holder of the loan must approve the deferment.

(c) At the holder's option, the borrower may also postpone payment of interest during the period of deferment.

(42 U.S.C. 294d, 294h)

§ 60.13 Interest.

(a) *Rate.* At the lender's option, the interest rate on the HEAL loan may be calculated on a fixed rate or on a variable rate basis. However, whichever method is selected must continue over the life of the loan, except where the loan is consolidated with another HEAL loan.

(1) Interest that is calculated on a fixed rate basis is determined for the life of the loan during the calendar quarter in which the loan is executed. It may not exceed the rate determined for that quarter by the Secretary under paragraph (a)(3) of this section.

(2) Interest that is calculated on a variable rate basis varies every calendar quarter throughout the life of the loan as the market price of U.S. Treasury bills changes. For any quarter it may not exceed the rate determined by the Secretary under paragraph (a)(3) of this section.

(3) For each calender quarter the Secretary determines the maximum annual HEAL interest rate by: (i) determining the average of the bond equivalent rates reported for the 91-day U.S. Treasury bills auctioned for the preceding calendar quarter, (ii) adding 3½ percentage points; and (iii) rounding that figure to the next higher one-eighth of one percent.

(4) The Secretary will announce the rate determined under paragraph (a)(3) of this section on a quarterly basis through a notice published in the FEDERAL REGISTER.

(b) *Compounding of interest.* As a general rule, unpaid accrued interest must be compounded semiannually and added to principal. However, a lender that permits a borrower to postpone payment of interest before the beginning of the repayment period or during periods of deferment or forbearance may refrain from semiannual compounding of interest and add accrued interest to principal only at the time repayment of principal begins or resumes. A lender may do so only if this practice does not result in interest being compounded more frequently than semiannually.

(c) *Payment.* Interest begins to accrue when a loan is disbursed and is payable in periodic installments over the life of the loan. However, a lender may permit a borrower to postpone payment of interest before the beginning of the repayment period or during a period of deferment or forbearance. In these cases, payment of interest must begin or resume on the date on which repayment of principal begins or resumes.

(d) *Usury laws.* The law provides that no provision of any Federal or State law that limits the rate or amount of interest payable on loans (commonly known as usury laws) shall apply to a HEAL loan.

(42 U.S.C. 294d, 294h; Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); Sec. 729 of the Public Health Service Act, 93 Stat. 582 (42 U.S.C. 294))

[43 FR 34324, Aug. 3, 1978. Redesignated and amended at 46 FR 8519, Jan. 27, 1981]

§ 60.14 The insurance premium.

(a) *General.* The Commissioner of Education insures each lender of a HEAL loan against losses it may suffer if the borrower defaults on his or her loan, dies, becomes totally and permanently disabled, or is adjudicated a bankrupt. For this insurance, the Commissioner charges each lender an insurance premium. The lender may pass along the cost of the insurance premium to the borrower in the form of a one time special charge with no subsequent adjustments required. The lender may bill the borrower separately for the insurance premium or may deduct an amount attributable to it from the loan proceeds. The lender must clearly identify to the borrower the amount of insurance premium and the method of calculation. The HEAL insurance coverage on a loan ceases to be effective after a 60-day default by the lender in the payment of the premium. Premiums are not refundable by the Commissioner, and need not be refunded by the lender to the borrower, even if the borrower graduates or withdraws from the school, or defaults, dies or becomes totally and permanently disabled prior to the anticipated graduation date.

(b) *Rate.* The rate of the insurance premium is one-fourth of 1 percent per year of the loan principal.

(c) *Method of calculation*—(1) *Student borrowers.* The lender must calculate the insurance premium on the basis of the period commencing the month beginning after the month the loan proceeds are disbursed to the student borrower and ending 9 full months after the month of the student's anticipated date of graduation.

(2) *Nonstudent borrowers.* The lender must calculate the insurance premium for nonstudent borrowers on the basis of the period commencing the month beginning after the month the loan proceeds are disbursed to the borrower and ending at the conclusion of the month preceding the month in which repayment of principal is expected to begin or resume on the borrower's previous HEAL loans.

(3) *Multiple installments.* In cases where the lender disburses the loan in multiple installments, the insurance premium is calculated for each disbursement.

(42 U.S.C. 294d, 294e, 294h)

§ 60.15 Other charges to the borrower.

(a) *Late charges.* The lender may, to the extent permitted by State law, require that the borrower pay a late charge if the borrower fails to pay all of a required installment payment within 10 days after its due date or fails to provide written evidence that verifies eligibility for the deferment of the payment. A late charge may not exceed 5 cents for each dollar of installment payment due or $5 for each payment, whichever is less.

(b) *Collection charges.* The lender may also require that the borrower pay the holder of the note for certain reasonable costs incurred by the holder or its agent in collecting any installment not paid when due. These costs may include attorney's fees, court costs, telegrams, and long-distance phone calls. The holder may not charge the borrower for the normal costs associated with preparing letters and making personal and local telephone contacts with the borrower. No charges other than those authorized by this section, including a service agency's fees for normal servicing of a loan, may be passed on to the borrower, either directly or indirectly.

(c) *Other loanmaking costs.* A lender may not pass any cost of making a HEAL loan other than the cost of the insurance premium on to the borrower.

(42 U.S.C. 294h)

§ 60.16 Power of attorney.

Neither a lender nor a school may obtain a borrower's power of attorney or other authorization to endorse a disbursement check on behalf of a borrower. The borrower must personally endorse the check and may not authorize anyone else to endorse it on his or her behalf.

(42 U.S.C. 294h)

§ 60.17 Security and endorsement.

A HEAL loan must be made without security. With one exception, it must also be made without endorsement. If a borrower is a minor and cannot under State law create a legally binding obligation by his or her own signature, a lender may require an endorsement by another person on the borrower's HEAL note. For puposes of this section, an "endorsement" means a signature of any party—other than the borrower—who is to assume either primary or secondary liability on the note.

(42 U.S.C. 294d, 294h)

§ 60.18 Consolidation of HEAL loans.

If a lender holds two or more HEAL loans made to the same borrower, the lender and the borrower may agree to consolidate the loans into a single HEAL loan obligation evidenced by one promissory note. In this situation, the lender must first inform the borrower of the effect of the consolidation on the interest rate and explain to the borrower that he or she is not required to agree to the consolidation.

(42 U.S.C. 294e, 294h)

§ 60.19 Forms.

All forms required under the HEAL program are provided by the Commissioner of Education. A school, a lender, or the Student Loan Marketing Association may change the format of any forms provided by the Commissioner. However, without prior approval of the Commissioner, a school, a lender, or the Student Loan Marketing Association may not change the provisions of any form. The Commissioner may prescribe the parties by whom the forms must be completed, the parties to whom the forms must be transmitted, and the times at which the forms must be transmitted. A school or lender, or an agent of either, may not sign in blank any form used in connection with a HEAL loan and it may not ask or permit a borrower to do so either.

(42 U.S.C. 294e, 294h)

§ 60.20 The Commissioner's collection efforts after payment of a default claim.

After paying a default claim on a HEAL loan, the Commissioner of Education attempts to collect against the borrower and any valid endorser in accordance with the Federal claims collection standards (4 CFR Parts 101-105). The Commissioner attempts collection of all unpaid principal and accrued interest, except in the following situations:

(a) *The borrower has a valid defense on the loan.* In this situation, the Commissioner refrains from collection against the borrower or endorser to the extent of any defense that either may have. Examples of a valid defense include expiration of the statute of limitations and infancy.

(b) *A school owes the borrower a refund for the period covered by the loan.* In this situation, the Commissioner refrains from collection to the extent of the unpaid refund if the borrower assigns to the Commissioner the right to receive the refund.

(c) *The school or lender is the subject of a lawsuit or Federal administrative proceeding.* In this situation, if the Commissioner determines that the proceeding involves allegations that, if proven, would provide the borrower with a full or partial defense on the loan, then the Commissioner may suspend collection activity on all or part of a loan until the proceeding ends. The Commissioner suspends collection activity only for so long as he or she believes that the proceeding is being energetically prosecuted in good faith and that the allegations that relate to the borrower's defense are reasonably likely to be proven.

(d) *The borrower dies, becomes totally and permanently disabled, or has the HEAL loan discharged in bankruptcy.* In this situation, the Commissioner terminates all collection activity against the borrower. If the borrower dies or becomes totally and permanently disabled, the Commissioner also terminates all collection activity against any valid endorser.

(42 U.S.C. 294f, 294h)

§ 60.21 Refunds.

(a) *Student authorization.* By applying for a HEAL loan, a student authorizes a participating school to make payment of a refund that is allocable to a HEAL loan directly to the original lender (or to a subsequent holder of the loan note, if the school has knowledge of the holder's identity).

(b) *Treatment of lenders.* (1) A holder of a HEAL loan must treat a refund payment received from a HEAL school as a downward adjustment in the amount of the principal amount of the loan.

(2) If a lender receives from a HEAL school a refund payment allocable to a loan no longer held by that lender, the

lender must transmit that payment to the party to whom it assigned the loan, together with an explanation as to its source. At the same time, the lender must provide to the borrower written notice of the transmission of this amount. However, if the lender does not have knowledge of the borrower's address, it must so advise the subsequent holder of the loan. The subsequent holder must then provide the borrower with written notice of its receipt of the refund payment.

(42 U.S.C. 294h, 294*l*)

Subpart D—The Lender

§ 60.30 Which organizations are eligible to apply to be HEAL lenders?

(a) A HEAL lender may make and hold loans under the HEAL program. In these regulations, the term "lender" includes a subsequent holder.

(b) The following types of organizations are eligible to apply to the Commissioner of Education to be HEAL lenders:

(1) A financial or credit institution (including a bank, savings and loan association, credit union, or insurance company) which is subject to examination and supervision in its capacity as a lender by an agency of the United States or of the State in which it has its principal place of business;

(2) A pension fund, approved by the Commissioner;

(3) An agency or instrumentality of a State; and

(4) A HEAL school.

(c) The Student Loan Marketing Association (popularly known as "Sallie Mae") is, by law, an eligible HEAL holder.

(42 U.S.C. 294a, 294e, 294h, 294j)

§ 60.31 The application to be a HEAL lender.

(a) In order to be a HEAL lender, an eligible organization must submit an application to the Commissioner of Education.

(b) In determining whether to enter into an insurance contract with an applicant and what the terms of that contract should be, the Commissioner may consider the following criteria:

(1) Whether the applicant is capable of complying with the requirements in the HEAL regulations applicable to lenders;

(2) The amount and rate of loans which are currently delinquent or in default, if the applicant has had prior experience with similar Federal or State student loan programs; and

(3) The finanical resources of the applicant.

(c) The Commissioner of Education may require an applicant to submit sufficient materials with its application so that the Commissioner may fairly evaluate it in accordance with these criteria.

(42 U.S.C. 294h)

§ 60.32 The HEAL lender insurance contract.

(a) (1) If the Commissioner of Education approves a lender's application to be a HEAL lender, the Commissioner and the lender sign an insurance contract. In general, the lender agrees to comply with all the laws, regulations, and other requirements applicable to its participation as a lender in the HEAL program. The Commissioner agrees to insure each eligible HEAL loan held by the lender against the borrower's default, death, total and permanent disability, or bankruptcy. The Commissioner's insurance covers 100 percent of the lender's losses on both unpaid principal and interest, except to the extent that a borrower may have a defense on the loan, other than infancy.

(2) HEAL insurance, however, is not unconditional. The Commissioner issues HEAL insurance on the implied representations of the lender that all the requirements for the initial insurability of the loan have been met. HEAL insurance is further conditioned upon compliance by all holders of the loan with the HEAL regulations applicable to lenders. The contract may contain a limit on the duration of the contract and the number or amount of HEAL loans a lender may make or hold. Each HEAL lender has either a standard insurance contract or a comprehensive insurance contract with the Commissioner.

(b) *Standard insurance contract.* A lender with a standard insurance contract must submit to the Commissioner a borrower's loan application for HEAL insurance on each loan that the lender determines to be eligible. The Commissioner notifies the lender whether the loan is or is not insurable and the amount of the insurance. No disbursements made on a loan made prior to the Commissioner's approval of that loan are insured.

(c) *Comprehensive insurance contract.* A lender with a comprehensive insurance contract may disburse a loan without submitting an individual borrower's loan application to the Commissioner for initial approval. All eligible loans made by a lender with this type of contract are automatically insured.

(42 U.S.C. 294a, 294b, 294d, 294e, 294f, 294h, 294k)

§ 60.33 Making a HEAL loan.

The loan-making process includes the processing of necesary forms, the approval of a borrower for a loan, the determination of the loan amount, the explanation to a borrower of his or her responsibilities under the loan, having the borrower execute the promissory note, and the disbursement of the loan proceeds. A lender may not delegate its loan-making functions to a servicing agency or other party. A lender may rely in good faith upon statements of a borrower and the HEAL school contained in application papers.

(a) *Processing of forms.* Before making a HEAL loan, a lender must determine that all required forms have been completed by the borrower, the HEAL school, and the lender.

(b) *Approval of borrower.* A lender may make a HEAL loan only to an eligible student or nonstudent borrower.

(c) *Determination of loan amount.* A lender may not make a HEAL loan in an amount that exceeds the permissible annual and aggregate maximums described in § 60.10.

(d) *Borrower interview.* (1) Before making an initial HEAL loan to a borrower, an employee of the lender should meet personally with the borrower in order to ensure that the borrower understands his or her rights and responsibilities under the loan. In particular, the lender should explain to the borrower that the loan must be repaid and that the loan proceeds may be applied toward educational expenses only. In addition, the lender must familiarize the borrower with the manner in which he or she must pay the interest that accrues prior to the beginning of the repayment period.

(2) In all cases, a lender must obtain from a borrower a signed statement, on a form provided by the Commissioner, describing the borrower's rights and responsibilities.

(e) *Promissory note.* Each loan must be evidenced by a promissory note. The Commissioner of Education periodically makes an approved promissory note form available to HEAL lenders. A lender must obtain the Commissioner's prior approval before it makes a HEAL loan evidenced by a promissory note containing any deviation from the provisions of the Commissioner's most current form. The lender must give the borrower a copy of each executed note.

(f) *Disbursement of HEAL Loan.* (1) A lender must disburse HEAL loan proceeds by means of a check or draft payable to a student borrower or, if authorized by the student in writing, jointly to the student and the HEAL school. Except where a lender is also a school, a lender must mail the check or draft to the school (to the attention of the school official named on the loan application) for delivery to the student borrower. A lender may not mail the check or draft to a school earlier than is reasonably necessary to meet the cost of education for the period for which the loan is made.

(2) The Commissioner encourages lenders to disburse HEAL loan proceeds in multiple installments that correspond to a borrower's needs over the period for which the loan is intended.

(3) A school lender must disburse the HEAL loan proceeds in one or more installments that correspond to a borrower's educational expenses over the period for which the loan is intended. However, in no case may the school lender disburse the proceeds earlier than is reasonably necessary to

meet the costs of education for the period for which the loan is made.

(42 U.S.C. 294f, 294h)

§ 60.34 HEAL loan servicing.

(a) *Borrower inquiries.* A lender must respond on a timely basis to written inquiries and other communications from a borrower and any endorser of a HEAL loan.

(b) *Conversion of loan to repayment status.* (1) When a lender determines that a borrower's loan is about to enter repayment, the lender must promptly contact the borrower in order to establish the terms of repayment.

(2) When establishing repayment terms, the lender should take into consideration the financial obligations and the current and potential income of the borrower. The lender should design a repayment schedule that retires the loan as soon as possible without leading to default caused by the borrower's inability to make payments.

(3) Terms of repayment are established in a written schedule that is made a part of, and subject to the terms of, the borrower's original HEAL note.

(4) The lender may not surrender the original promissory note to the borrower until the loan is paid in full. At that time, the lender must give the borrower the original promissory note.

(42 U.S.C. 294f, 294h)

§ 60.35 HEAL loan collection.

A lender must exercise due diligence in the collection of a HEAL loan with respect to both a borrower and any endorser. In order to exercise due diligence, a lender must implement the following procedures when a borrower fails to honor his or her payment obligation:

(a) When a borrower is delinquent in making a payment, the lender must remind the borrower within 15 working days of the date the payment was due by means of a letter, telephone call, or personal contact. If payments do not resume, the lender must attempt to contact both the borrower and any endorser at least three more times at regular intervals during the following 4-month period. These contacts should become progressively more firm in tone.

(b) Whenever a lender does not know the borrower's correct address, the lender must attempt to locate the borrower through normal commercial collection techniques, including contacting any endorser or other individual named on the borrower's application. If these efforts are unsuccessful, the lender must attempt to learn the borrower's correct address through use of the Office of Education preclaim assistance. This preclaim assistance consists of attempts to locate a missing borrower. The Office of Education advises the lender of the results of its efforts to locate the missing borrower. The Commissioner of Education does not pay insurance on a default claim if the lender failed to request preclaim assistance where the borrower's address was unknown.

(c) When a borrower is 60 days delinquent in making a payment, the lender must request preclaim assistance from the Office of Education. This preclaim assistance consists of a series of letters to the borrower urging the borrower to contact the lender and resume payments. The Commissioner of Education does not pay insurance on a default claim if the lender failed to request preclaim assistance in this situation.

(d) If a lender does not sue the borrower, it must send a final demand letter to the borrower and any endorser at least 30 days before it files a default claim. However, the lender need not send a final demand letter to a borrower whose address is unknown.

(e) If a lender sues a defaulted borrower or endorser, it may first apply the proceeds of any judgment against its reasonable attorney's fees and court costs, whether or not the judgment provides for these fees and costs.

(42 U.S.C. 294f, 294h)

§ 60.36 Consequence of using an agent.

The delegation of functions to a servicing agency or other party does not relieve a lender of its responsibilities under the HEAL program.

(42 U.S.C. 294f, 294h)

§ 60.37 Forbearance.

(a) The Commissioner of Education encourages a HEAL lender to grant forbearance for the benefit of a borrower in order to prevent a borrower from defaulting on his or her payment obligations. "Forbearance" means an extension of time for making loan payments or the acceptance of smaller payments than were previously scheduled. A lender may grant forbearance whenever unemployment, health, other personal problems, or study that is ineligible for deferment temporarily affects the borrower's ability to make scheduled payments on a HEAL loan.

(b) A lender may exercise forbearance in accordance with terms that are consistent with the minimum annual payment requirement and the 15- and 23-year limitations on length of repayment (described in § 60.11) if the lender and borrower agree in writing to the new terms.

(c) A lender may also exercise forbearance for a period of up to 6 months in accordance with terms that are inconsistent with the minimum annual payment requirement and the 15- and 23-year limitations on length of repayment (described in § 60.11) if the lender complies with the requirements listed below. Subsequent renewals of the forbearance must also be documented in accordance with the following requirements:

(1) The lender must reasonably believe that the borrower intends to repay the loan but is currently unable to make payments in accordance with the terms of the loan note. The lender must state the basis for its belief in writing and maintain that statement in its loan file on that borrower.

(2) Both the borrower and an authorized official of the lender must sign a written agreement of forbearance.

(3) If the agreement between the borrower and lender provides for deferment of all payments, the lender must contact the borrower at least every 3 months during the period of forbearance in order to remind the borrower of the outstanding obligation to repay.

(42 U.S.C. 294f, 294h)

§ 60.38 Assignment of a HEAL loan.

A HEAL note may not be assigned except to another HEAL lender or the Student Loan Marketing Association (popularly known as "Sallie Mae"). In this section "seller" means any kind of assignor and "buyer" means any kind of assignee.

(a) *Procedure.* A HEAL note assigned from one lender to another must be subject to a blanket endorsement together with other HEAL notes being assigned or must individually bear effective words of assignment. Either the blanket endorsement or the HEAL note must be signed and dated by an authorized official of the seller. The buyer must notify the Commissioner of Education of the assignment within 30 days of the transaction. The buyer must assure that the borrower is notified if the assignment results in the borrower being required to make installment payments or direct other matters connected with the loan to a party other than the seller. The notice to the borrower must contain a clear statement of all the borrower's rights and responsibilities which arise from the assignment of the loan, including a statement regarding the consequences of making payments to the seller subsequent to receipt of the notice.

(b) *Risks assumed by the buyer.* Upon acquiring a HEAL loan, a new holder assumes responsibility for the consequences of any previous violations of applicable statutes, regulations, or the terms of the note. A HEAL note is not a negotiable instrument, and a subsequent holder is not a holder in due course. If the borrower has a valid legal defense that could be asserted against the previous holder, the borrower can also assert the defense against the new holder. In this situation, if the new holder files a default claim on a loan, the Commissioner denies the default claim to the extent of the borrower's defense. Furthermore, when a new holder files a claim on a HEAL loan, it must provide the Commissioner with the same documentation that would have been required of the original lender.

(c) *Warranty.* Nothing in this section precludes the buyer of a HEAL loan from obtaining a warranty from the seller covering certain future reductions by the Commissioner in computing the amount of insurable loss, if any, on a claim filed on the loan. The warranty may only cover reductions which are attributable to an act or failure to act of the seller or other previous holder. The warranty may not cover matters for which the buyer is charged with responsibility under the HEAL regulations.

(42 U.S.C. 294a, 294e, 294h)

§ 60.39 Death and disability claims.

(a) *Death.* If a borrower dies, his or her obligation to make any further payments of principal and interest on a HEAL loan is canceled. The holder of the loan may not attempt to collect on the loan from the borrower's estate or any endorser. The holder may make a determination that the borrower has died on the basis of a death certificate or other proof of death which is acceptable under applicable State law. If a death certificate or other acceptable proof of death is not available, the borrower's obligation on the loan is canceled on account of death only upon a determination by the Commissioner of Education on the basis of other evidence that the Commissioner finds conclusive. The holder must return to the sender any payments received from the estate of the borrower or paid on behalf of the borrower after the date of death.

(b) *Disability.* (1) If a borrower becomes totally and permanently disabled, his or her obligation to make any further payments of principal and interest on a HEAL loan is canceled. A borrower is totally and permanently disabled if he or she is unable to engage in any substantial gainful activity because of a medically determinable impairment, which the Commissioner expects to continue for a long and indefinite period of time or to result in death.

(2) After being notified by the borrower or the borrower's representative that the borrower claims to be totally and permanently disabled, the holder of the loan may not attempt to collect on the loan from the borrower or any endorser. The holder must promptly request that the Commissioner determine whether a borrower has become totally and permanently disabled. With its request, the holder must submit medical evidence no more than 4 months old that it has obtained from the borrower or the borrower's representative.

(3) If the Commissioner determines that the borrower is totally and permanently disabled, the lender must return to the borrower any payments that it may have received after being notified that the borrower claims to be totally and permanently disabled.

(42 U.S.C. 294h, 294k)

§ 60.40 Procedures for filing claims.

(a) A lender must file an insurance claim on a form provided by the Commissioner of Education. The lender must attach to the claim all documentation which the Commissioner may require. Failure to submit the required documentation may result in a claim not being honored. The Commissioner may also deny a claim that is not timely filed. The Commissioner requires for all claims the following documentation:

(1) The original promissory note;

(2) The loan application; and

(3) A payment history, if any.

(b) The Commissioner's payment of a claim is contingent upon receipt of all required documentation and an assignment to the United States of America of all right, title, and interest of the lender in the note underlying the claim. The lender must warrant that the loan is eligible for HEAL insurance.

(c) In addition, the lender must comply with the following requirements for the filing of default, death, disability, and bankruptcy claims:

(1) *Default claims.* (i) Unless a lender has notified the Commissioner that it has filed suit against a defaulted borrower, it must file a default claim with the Commissioner within 90 days after a loan has been determined to be in default. Default means that persistent failure of the borrower to make a payment when due, or to comply with other terms of the note or other written agreement evidencing a loan under circumstances where the Commissioner finds it reasonable to

conclude that the borrower no longer intends to honor the obligation to repay. In the case of a loan repayable (or on which interest is payable) in monthly installments, this failure must have persisted for 120 days. In the case of a loan repayable (or on which interest is payable) in less frequent installments, this failure must have persisted for 180 days.

(ii) In addition to the documentation required for all claims, the lender must submit with its default claim the following:

(A) The repayment schedule;

(B) A collection history;

(C) A final demand letter, if required; and

(D) The original or a copy of all correspondence relevant to the amount owed by the borrower (whether or not received by the original lender, a subsequent holder, or an independent servicing agent).

(iii) If the lender files a default claim on a loan and subsequently receives a notice of the first meeting of creditors in the borrower's bankruptcy, the lender must promptly forward that notice to the Office of Education. The lender may not file a proof of claim with the bankruptcy court in this situation.

(2) *Death claims.* A lender must file a death claim with the Commissioner within 60 days after the lender determines that a borrower is dead. In addition to the documentation required for all claims, the lender must submit with its death claim those documents which formed the basis for its determination of death.

(3) *Disability claims.* A lender must file a disability claim with the Commissioner within 60 days after it is notified that the Commissioner has determined a borrower to be totally and permanently disabled. In addition to the documentation required for all claims, the lender must submit with its claim evidence of the Commissioner's determination.

(4) *Bankruptcy claims.* A lender must file a bankruptcy claim with the Commissioner within 60 days after the lender receives a notice of the first meeting of creditors in a borrower's bankruptcy proceeding. The lender must file a proof of claim with the bankruptcy court. In addition to the documentation required for all claims, the lender must submit with its claim to the Commissioner the following:

(i) The repayment schedule;

(ii) A collection history, if any;

(iii) An assignment to the United States of America of its proof of claim;

(iv) All pertinent documents sent to or received from the bankruptcy court; and

(v) A statement of any facts of which the lender is aware that may form the basis for an objection to the bankrupt's discharge or an exception to the discharge. Section 733(g) of the Public Health Service Act provides that a HEAL loan may be discharged in bankruptcy only after the expiration of the 5-year period beginning when the repayment period for the loan begins.

(42 U.S.C. 294f, 294h)

§ 60.41 Determination of amount of loss on claims.

(a) *General rule.* HEAL insurance covers the unpaid balance of principal and interest on an eligible HEAL loan. In determining whether to approve an insurance claim for payment, the Commissioner of Education considers legal defects affecting the initial validity or insurability of the loan. The Commissioner also deducts from a claim any amount that is not a legally enforceable obligation of the borrower except to the extent that the defense of infancy applies. The Commissioner further considers whether all holders of the loan have complied with the requirements of the HEAL regulations, including those concerned with the making, servicing, and collecting of loans, the timely filing of claims, and the submission of documents with a claim.

(b) *Special rules for loans acquired by assignment.* If a claim is filed by a lender that obtained a loan by assignment, that lender is not entitled to any payment under this section greater than that to which a previous holder would have been entitled. In particular, the Commissioner deducts from the claim any amounts that are attributable to payments made by the borrower to a prior holder of the loan before the borrower received proper notice of the assignment of the loan.

(c) *Special rules for loans made by school lenders.* (1) If the loan for which a claim is filed was originally made by a school and the claim is filed by that school, the Commissioner deducts from the claim an amount equal to any unpaid refund that the school owes the borrower.

(2) If the loan for which a claim is filed was originally made by a school but the claim is filed by another lender that obtained the note by assignment, the Commissioner deducts from the claim an amount equal to any unpaid refund that the school owed the borrower prior to the assignment.

(d) *Circumstances under which defects in claims may be cured or excused.* The Commissioner may permit a lender to cure certain defects in a specified manner as a condition for payment of a default claim. The Commissioner may excuse certain defects if the holder submitting the default claim satisfies the Commissioner that the defect did not contribute to the default or prejudice the Commissioner's attempts to collect on the loan from the borrower. The Commissioner may also excuse certain defects if the defect arose while the loan was held by another lender and the holder submitting the default claim satisfies the Commissioner that the assignment of the loan was an arm's length transaction, that the present holder did not know of the defect at the time of the sale, and that the present holder could not have become aware of the defect through an examination of the loan documents.

(e) *Payment of insured interest.* The payment on an approved claim covers unpaid interest that accrues through the date the Commissioner approves the claim and authorizes payment, subject to two exceptions:

(1) If the lender failed to submit a claim within the required period after the borrower's default, death, disability, or bankruptcy, the Commissioner does not pay interest that accrued between the end of that period and the date the Commissioner received the claim.

(2) If the Commissioner returned the claim to the lender for additional documentation necessary for the approval of the claim, the Commissioner pays interest only for the first 30 days following the return of the claim to the lender.

(42 U.S.C. 294b, 294d, 294f, 294h)

§ 60.42 Records, reports, and inspection requirements for HEAL lenders.

(a) *Records.* (1) A lender must keep complete and accurate records of each HEAL loan which it holds. The records must be organized in a way that permits ready identification of the current status of each loan. The required records include:

(i) The loan application;

(ii) The original promissory note;

(iii) The repayment schedule agreement;

(iv) Evidence of each disbursement of loan proceeds;

(v) Notices of changes in a borrower's address and status as a full-time student;

(vi) Evidence of the borrower's eligibility for a deferment;

(vii) The borrower's signed statement describing his or her rights and responsibilities in connection with a HEAL loan;

(viii) The documents required for the exercise of forbearance; and

(ix) Documentation of the assignment of the loan.

(2) The lender must maintain for each borrower a payment history showing the date and amount of each payment received on the borrower's behalf, and the amounts of each payment attributable to principal and interest. A lender must also maintain for each loan a collection history showing the date and subject of each communication with a borrower or endorser for collection of a delinquent loan. Furthermore, a lender must keep any additional records which are necessary to make any reports required by the Commissioner of Education.

(3) A lender must retain the records required for each loan for not less than 3 years following the date the loan is repaid in full by the borrower. However, in particular cases the Commissioner may require the retention of

records beyond this minimum period. A lender must keep the original copy of an unpaid promissory note, but may store all other records in microform or computer format.

(b) *Reports.* A lender must submit reports to the Commissioner at the time and in the manner as the Commissioner may reasonably require.

(c) *Inspections.* Upon request, a lender must afford the Secretary of Health, Education, and Welfare, the Comptroller General of the United States, and any of their authorized representatives access to its records in order to assure the correctness of its reports.

(42 U.S.C. 294e, 294h)

§ 60.43 Limitation, suspension, or termination of the eligibility of a HEAL lender.

(a) The Commissioner of Education may limit, suspend, or terminate the eligibility under the HEAL program of an otherwise eligible lender that violates any provision of title VII, part C, subpart I of the Public Health Service Act, as amended (42 U.S.C. 294-294*l*), the HEAL regulations, or agreements with the Commissioner concerning the HEAL program. The Commissioner takes this action in accordance with procedures for the limitation, suspension, or termination of the eligibility of lenders under the Federal insured student loan program which are set forth in 45 CFR Part 177.

(b) This section does not apply to a determination that a HEAL lender fails to meet the statutory definition of an "eligible lender."

(c) This section also does not apply to administrative action by the Department of Health, Education, and Welfare based on any alleged violation of:

(1) Title VI of the Civil Rights Act of 1964, which is governed by 45 CFR Parts 80 and 81;

(2) Title IX of the Education Amendments of 1972, which is governed by 45 CFR Part 86; or

(3) The Family Educational Rights and Privacy Act of 1974 (section 438 of the General Education Provisions Act, as amended), which is governed by 45 CFR Part 99.

(42 U.S.C. 294f, 294h)

Subpart E—The School

§ 60.50 Which schools are eligible to be HEAL schools?

(a) In order to participate in the HEAL program, a school must enter into a written agreement with the Commissioner of Education. In the agreement, the school promises to comply with provisions of the HEAL law and the HEAL regulations. In order to initially enter into this agreement and in order for the agreement to remain in effect, a school must satisfy the following requirements:

(1) The school must be legally authorized within a State to conduct a course of study leading to one of the following degrees:

Doctor of Medicine.
Doctor of Osteopathy.
Doctor of Dentistry or equivalent degree.
Bachelor or Master of Science in Pharmacy or equivalent degree.
Doctor of Optometry or equivalent degree.
Doctor of Veterinary Medicine or equivalent degree.
Doctor of Podiatry or equivalent degree.
Graduate degree in Public Health or equivalent degree.

For the purposes of this section, the term "State" includes, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

(2) The school must be accredited by a recognized agency approved for that course of study by the Commissioner of Education. If a school is not eligible for accreditation solely because it is too new, that school may nevertheless be eligible for the HEAL program. A new school is eligible if the Commissioner determines that it can reasonably expect to be accredited before the beginning of the academic year following the normal graduation date of its first entering class. The Commissioner makes this determination after consulting with the appropriate accrediting agency and receiving reasonable assurance to that effect.

(3) The school must have received a capitation grant under section 770 of the Public Health Service Act for the preceding fiscal year. If the school did not receive a grant, it is nevertheless eligible for the HEAL program if it was eligible to receive a grant or if it met all the requirements to receive a grant except the requirement contained in section 771(b)(3) of the Public Health Service Act.

(b) If a HEAL school undergoes a change of controlling ownership or form of control, its agreement automatically expires at the time of that change. The school must enter into a new agreement with the Commissioner in order to continue its participation in the HEAL program.

(42 U.S.C. 294h, 294j)

§ 60.51 The student loan application.

(a) A school must accurately and completely fill out its portion of a student's loan application. In general, the information requested of the school pertains to the student's eligibility for a loan, the student's estimated cost of attendance for the period for which the loan is sought, and other financial aid (exclusive of family contribution) of which the school is aware that has been awarded the student for that period.

(b) In addition, a school of medicine, osteopathic medicine or dentistry must provide a special authorization that a student may receive a loan. A school of medicine, osteopathic medicine or dentistry may not authorize more that 50 percent of the students in each class to receive a HEAL loan in any 12-month academic year. Each school of medicine, osteopathic medicine, or dentistry may establish its own procedures for determining which students are authorized to receive HEAL loans.

(42 U.S.C. 294h, 294*l*)

§ 60.52 The student's loan check.

(a) When a school receives from a HEAL lender a loan disbursement check or draft payable to one of its students, it must do the following:

(1) If the school receives the instrument after the student is enrolled, it must promptly deliver the instrument to the student.

(2) If the school receives the instrument before the student is enrolled, it must hold the instrument and deliver it to the student at the time of enrollment. However, if the student is unable to meet educational expenses due before the time of enrollment, the school may send the instrument to the student in time to meet those expenses.

(b) When a school receives from a HEAL lender a loan disbursement check or draft payable jointly to the school and to one of its students, it must do the following:

(1) If the school receives the instrument after the student is enrolled, it must either:

(i) Endorse the instrument and transmit it to the student; or

(ii) Obtain the student's endorsement, retain that portion of funds due the school, and disburse the remaining funds to the student.

(2) If the school receives the instrument before the student is enrolled, it must, prior to endorsing the instrument, send the instrument to the student for the student to endorse it and return it to the school. The school may then retain that portion of funds then due the school but must hold the remaining funds for disbursement to the student at the time of enrollment. However, if the student is unable to meet other educational expenses due before the time of enrollment, the school may obtain the student's endorsement and disburse to the student that portion of funds required to meet these other educational expenses.

(c) If a school determines that a student does not plan to enroll, the school must return a loan disbursement check or draft to the lender within 30 days of its determination.

(42 U.S.C. 294h, 294*l*)

§ 60.53 Notification to lender of change in enrollment status.

Each school must establish and implement procedures under which it notifies the holder of a student's HEAL loan of a change in the student's enrollment status. Those procedures must include giving that notice within

60 days following the change in status. Each notice must contain the date of the student's graduation, formal withdrawal, or failure to enroll as scheduled for any academic period as a full-time student. Each notice must also contain the student's latest known permanent and temporary addresses. The procedures must provide that if the school does not know the identity of the current holder of the HEAL loan, it notifies the HEAL Program Office of the U.S. Office of Education of a change in the student's enrollment status.

(42 U.S.C. 294h, 294*l*)

§ 60.54 Payment of refunds by schools.

A participating school must pay that portion of a refund that is allocable to a HEAL loan directly to the original lender (or to a subsequent holder of the loan note, if the school has knowledge of the holder's identity). At the same time, the school must provide to the borrower written notice that it is doing so.

(42 U.S.C. 294h, 294*l*)

§ 60.55 Administrative and fiscal procedures.

Each school must establish and maintain administrative and fiscal procedures necessary to achieve the following objectives:

(a) Proper and efficient administration of the funds received from students who have HEAL loans;

(b) Protection of the rights of students under the HEAL program;

(c) Protection of the United States from unreasonable risk of loss due to defaults; and

(d) Compliance with applicable requirements for HEAL schools.

(42 U.S.C. 294h, 294*l*)

§ 60.56 Records.

(a) Each school must maintain an easily retrievable record with respect to each student who has a HEAL loan containing all of the following items of information that are applicable:

(1) The student's name;

(2) The student's address;

(3) The student's academic standing;

(4) The student's period of attendance;

(5) The name of the HEAL lender;

(6) The amount of the HEAL loan;

(7) The period for which the HEAL loan was intended;

(8) The date the school receives the HEAL check or draft and the date it either gives it to the student or returns it to the lender (in the case of a school that is not the lender);

(9) The amount and source of other financial assistance (exclusive of family contribution) received by the student for the period for which the HEAL loan was made;

(10) The date the school disburses a loan to a student (in the case of a school that is the lender);

(11) The date the school signs the loan check or draft (in the case of a school that is a copayee);

(12) The amount of tuition, fees and other charges paid by the student to the school for the academic period covered by the loan and the dates of payment;

(13) A copy of each form used by the school in connection with the loan; and

(14) The student's postgraduate destination.

(b) The school must maintain the record for not less than 3 years (unless otherwise directed by the Commissioner of Education) following the date the student graduates, withdraws or fails to enroll as a full-time student. The school may store the record in microform or computer format.

(42 U.S.C. 294h, 294*l*)

§ 60.57 Reports.

A school must submit reports to the Commissioner of Education at the times and in the manner the Commissioner may reasonably prescribe. The school must retain a copy of each report for not less than 3 years following the report's completion, unless otherwise directed by the Commissioner. A school must also make available to a HEAL lender, upon the lender's request, the name, address, postgraduate destination and other reasonable identifying information for each of the school's students who has a HEAL loan.

(42 U.S.C. 294h, 294*l*)

§ 60.58 Federal access to school records.

For the purposes of audit and examination, a HEAL school must provide the Secretary of Health, Education, and Welfare, the Comptroller General of the United States, and any of their authorized representatives access to the records that the school is required to keep and to any documents and records pertinent to the administration of the HEAL program.

(42 U.S.C. 294h, 294*l*)

§ 60.59 Records and Federal access after a school is no longer a HEAL school.

In the event a school ceases to participate in the HEAL program, the school (or its successor, in the case of a school which undergoes a change in ownership) must retain all required HEAL records and provide the Secretary of Health, Education, and Welfare, the Comptroller General of the United States, and any of their authorized representatives access to them.

(42 U.S.C. 294h, 294*l*)

§ 60.60 School audits.

(a) A school's transactions relating to its participation in the HEAL program shall be audited by the school or at the school's direction by a Certified Public Accountant or by a Licensed Public Accountant licensed before December 31, 1970. The purpose of these audits is to determine, at a minimum, the fiscal integrity of financial transactions and reports and whether those transactions are in compliance with applicable laws and regulations. Audits shall be scheduled with reasonable frequency, usually annually, but not less than once every 2 years, considering the size and complexity of the activity of the program. Each audit must cover the entire period of time that has elapsed since the last audit that was performed.

(b) The required audit report must be submitted for review to the regional office of the Department of Health, Education, and Welfare Audit Agency serving the region in which the school is located. The school must afford the Secretary of Health, Education, and Welfare, the Comptroller General of the United States, and any of their authorized representatives access to the records or other documents necessary to review the results of those audits.

(42 U.S.C. 294h, 294*l*)

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FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

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Table of CFR Titles and Chapters
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Material Approved for Incorporation by Reference

The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 CFR Part 51 the incorporation by reference of the following publications. For more information on incorporation by reference, see the preliminary pages of this volume.

42 CFR CHAPTER I (PARTS 1-60)
PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

	42 CFR
American Insurance Association Publications Department, 85 John St., New York, NY 10038	
National Building Code, 1976 Ed.	Part 36, Subpart H, Appendix A(a)
American Nurses' Association 2420 Pershing Rd., Kansas City, MO 64108 Also available from Emergency Department Nurses' Association, 666 N. Lake Shore Dr., Chicago, IL 60611	
ANA Publication Code MS-5 10M 9/75 Standards of Emergency Nursing Practice.	57.2106(b)(3)(i)
American Society of Heating, Refrigerating and Air Conditioning Engineers United Engineer Center, 345 E. 47th St., New York, NY 10017	
Handbook of Fundamentals, 1977	Part 36, Subpart H, Appendix A(b)(1); 52b.11(b)(1)
American Society of Mechanical Engineers United Engineer Center, 345 East 47th St., New York, NY 10017	
Boiler and Pressure Vessel Code, 1977 Ed., with Summer 1980 addendum, Section 8, Division I.	Part 36, Subpart H, Appendix A(b)(3)
National Plumbing Code, 1955	Part 36, Subpart H, Appendix A(b)(2)
Compressed Gas Association 500 Fifth Ave., New York, NY 10036	
Pamphlet P-2.1. Standard for Medical-Surgical Vacuum Systems in Hospitals (1967).	52b.11(b)(4)
General Services Administration, Public Buildings Services Office of Design and Construction, 18th & F Sts., NW., Washington, DC 20405	
GSA Accessibility Standard (PBS (PCD): DG6, Oct. 14, 1980)	36.110(b)(10); 51c.503(a)(7)(iii)(A); 52b.8(j)
International Conference of Building Officials 5360 South Workman Mill Rd., Whittier, CA 90601	
Uniform Building Code, 1979 Ed.	52b.11(g); 52b.11(a); Part 36, Subpart H, Appendix A(g)

National Association of Plumbing-Heating-Cooling Contractors
1016 20th St., NW., Washington, DC 20036

National Standard Plumbing Code, 1980 Ed.	52b.11(b)(2)

National Council on Radiation Protection and Measurement
P.O. Box 30175, Washington, DC 20014

Also available for examination at ALOSH, 944 Chestnut Ridge Rd., Morgantown, WV 26505 and National Institute for Occupational Safety and Health, 5600 Fishers Ln., Rockville, MD 20857

NCRP Report No. 33, Medical X-ray and Gamma-Ray Protection for Energies Up to 10 MeV—Equipment Design and Use (issued Feb. 1, 1968).	Part 36, Subpart H, Appendix A(f); 37.43; 52b.11(f)
NCRP Report No. 35, Dental X-ray Protection (issued Mar. 9, 1970)	Part 36, Subpart H, Appendix A(f)
NCRP Report No. 36, Radiation Protection in Veterinary Medicine (issued Aug. 15, 1970).	Part 36, Subpart H, Appendix A(f)
NCRP Report No. 48, Medical Radiation Protection for Medical and Allied Health Personnel (issued Aug. 1, 1976).	37.43
NCRP Report No. 49, Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma-Rays of up to 10 MeV (issued Sept. 15, 1976).	37.43; Part 36, Subpart H, Appendix A(f); 52b.11(f)

National Fire Protection Association
Batterymarch Park, Quincy, MA 02269

NFPA No. 56F, 1977, Standard for Non-Flammable Medical Gas Systems.	52b.11(b)(3)
NFPA No. 70, 1981, National Electric Code	Part 36, Subpart H, Appendix A(e); 52b.11(e)
NFPA No. 101, 1976, Life Safety Code	Part 36, Subpart H, Appendix A(c); 51c.503(a)(7)(iii)(B); 52b.11(c) and (d)

Transportation Department, National Highway Traffic Safety Administration
Washington, DC 20590

Also available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Basic Training Course/Emergency Medical Technician (2nd Ed.) Course Guide 1977 (DOT Pub. No. HS 802534 through 536).	57.2106(b)(1)(i)
National Training Course Guide for Emergency Medical Technician—Paramedic, 1977 (DOT Pub. No. HS 802437) Appendix A.	57.2106(b)(2)(i)
National Training Course Guide for Emergency Medical Technician—Paramedic, 1977 (DOT Pub. No. HS 802437) Appendices B and C.	57.2106(b)(2)(ii)

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Table of CFR Titles and Chapters

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Title 1—General Provisions

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I	Administrative Committee of the Federal Register (Parts 1-49)
II	Office of the Federal Register (Parts 50-299)
III	Administrative Conference of the United States (Parts 300-399)
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List of CFR Sections Affected

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